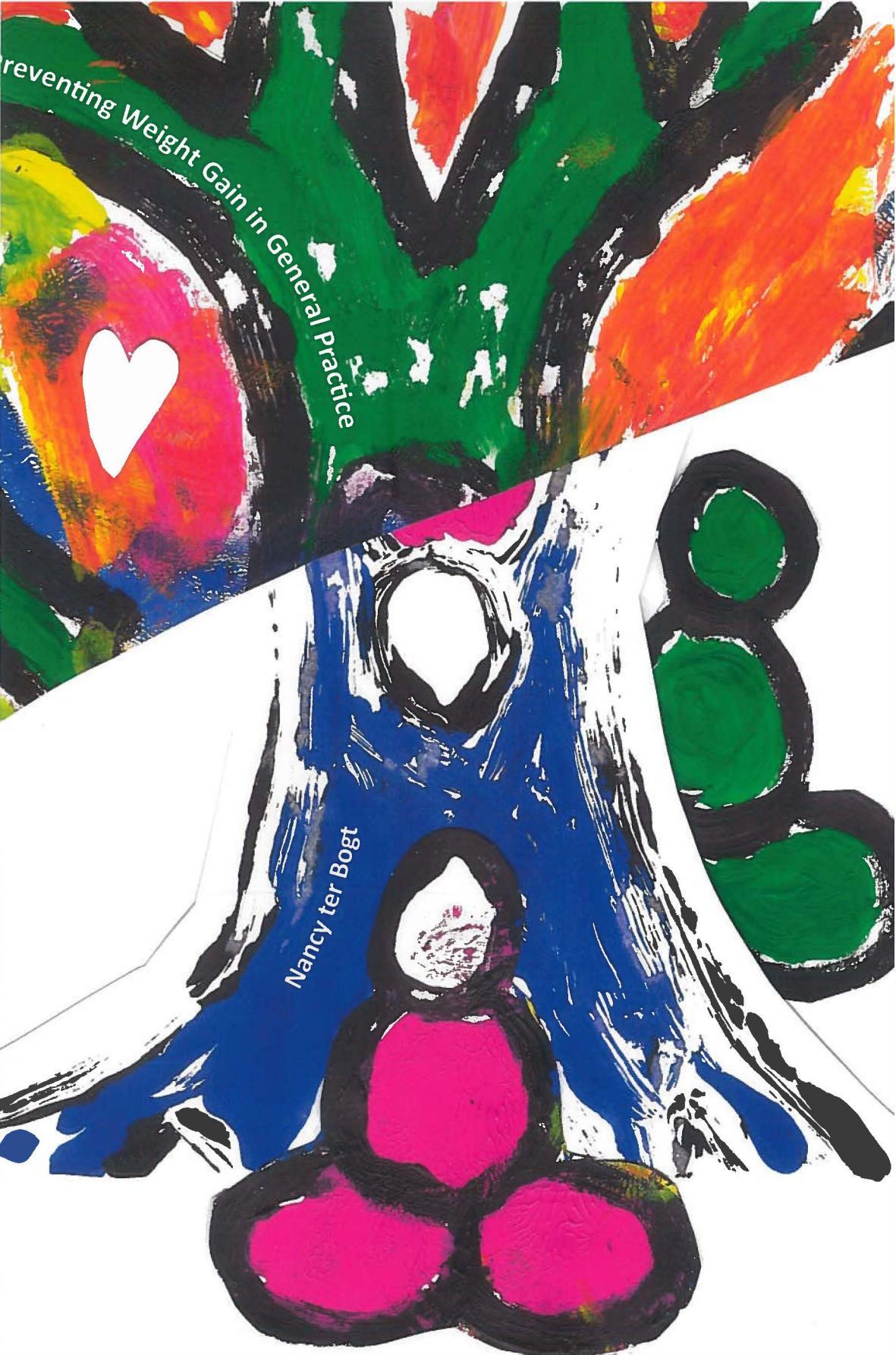
Preventing weight gain in general practice : lifestyle counseling by nurse practictioners compared with usual care by general practitioners

Bogt, Nancy Cilia Wilhelmina ter


reventing Weight Gain in General Practice
Nancy ter Bogt

PREVENTING WEIGHT GAIN IN GENERAL PRACTICE

Lifestyle counselling by nurse practitioners compared with usual care by general practitioners

N.C.W. ter Bogt

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Beschrijving: De persoon voor de boom mediteert om de ideale levensvorm te ontdekken. De boom staat symbool voor het innerlijke leven, de groene stenen voor uiterlijke vorm.
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Stellingen

behorende bij het proefschrift

PREVENTING WEIGHT GAIN IN GENERAL PRACTICE

1. De GOAL interventie draagt bij aan de preventie van Diabetes Mellitus type 2 (dit proefschrift)

2. Het vooruitzicht om de leefstijl te gaan aanpassen levert gewichtstoename op (dit proefschrift)

3. In het geval van afvallen heeft ervaring hiermee een ongunstig effect (dit proefschrift)

4. Ruim de helft van de hoeveelheid gewichtsafname blijft behouden (dit proefschrift)

5. Tevredenheid over de GOAL interventie wordt (mede) bepaald door het ervaren succes (dit proefschrift)

6. De praktijkondersteuner zorgt ervoor dat deelnemers meer tijd aan wandelen spenderen (dit proefschrift)

7. One polypill a day keeps the doctor away (Wald NJ, Law MR. BMJ Jun. 28, 2003)

8. Wa'j vroeg leert mo'j lang ontholde (Achterhoekse wijsheid)

9. The proof of the pudding is in the eating (Traced back to 1300 and popularised by Cervantes in 1605)

10. The boat is safer anchored at the port; but that's not the aim of boats (Paulo Coelho, as a tweet)

Nancy ter Bogt, 2011

RIJKSUNIVERSITEIT GRONINGEN

PREVENTING WEIGHT GAIN IN GENERAL PRACTICE

Lifestyle counselling by nurse practitioners compared
with usual care by general practitioners

Proefschrift

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Nancy Cilia Wilhelmina ter Bogt
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Promotor:	Prof. dr. K. van der Meer
Copromotores:	Dr. ir. W.J.E. Bemelmans Dr. F.W. Beltman
Beoordelingscommissie:	Prof. dr. J.J. van Binsbergen Prof. dr. J.W. Groothoff Prof. dr. J.C. Seidell

Paranimfen:	Siebrig Schokker
	Siska van der Vlugt

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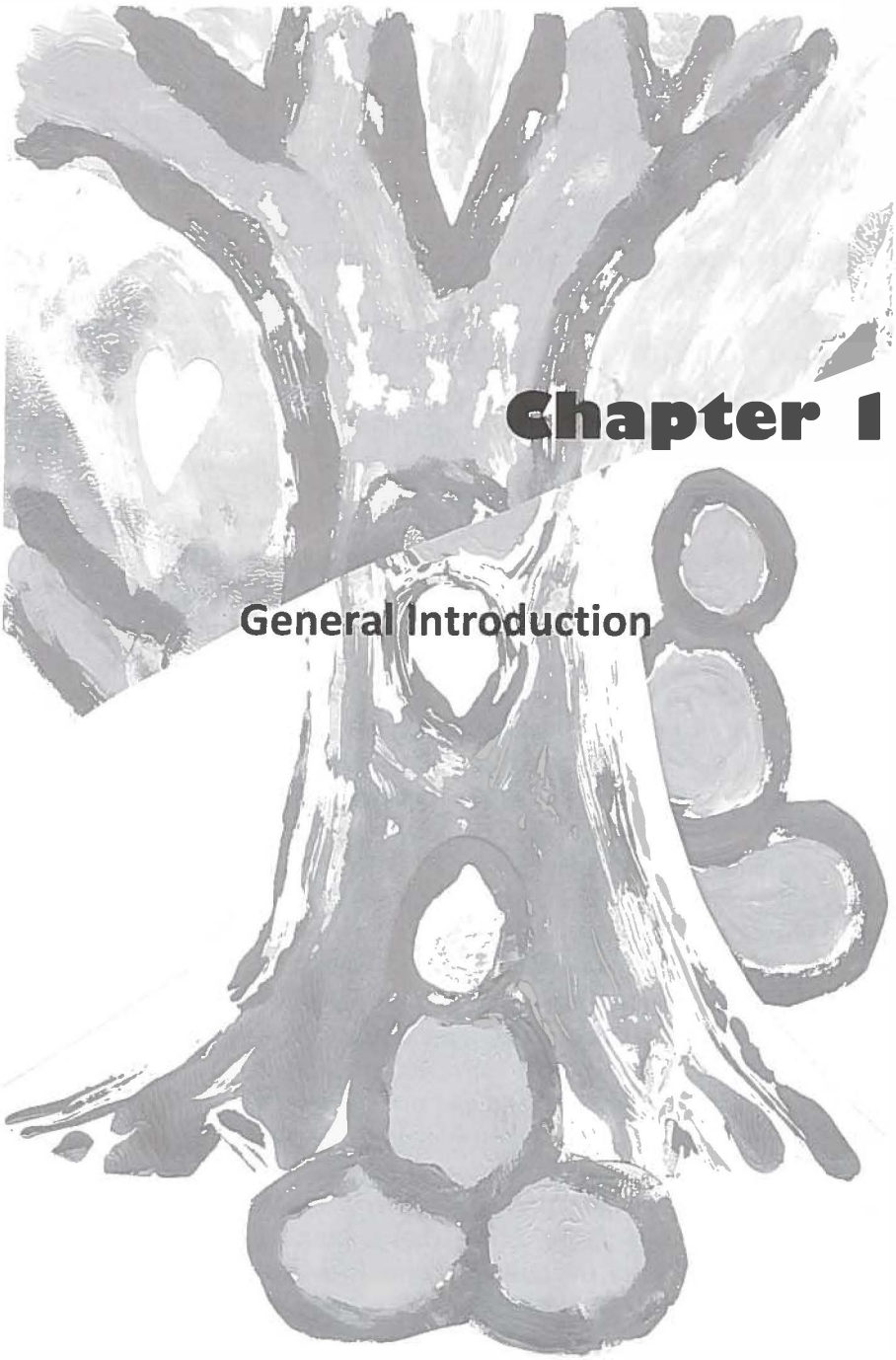


Chapter 1

General Introduction

GENERAL INTRODUCTION

Definitions of overweight and obesity

According to the definitions of the World Health Organization the prevalence of overweight and obesity is commonly assessed by using body mass index (BMI), defined as the weight in kilograms divided by the square of the height in metres (kg/m^2). A BMI over 25 kg/m^2 is defined as overweight, and a BMI of over 30 kg/m^2 as obese [1]. Obesity is also often defined simply as a condition of abnormal or excessive fat accumulation in adipose tissue, to the extent that health may be impaired [2]. But not only the amount of excess fat that is stored is important, also the regional distribution of that fat within the body. Abdominal fat is a generator of risk factors for cardiovascular disease (CVD) and diabetes [3]. A review of Depres demonstrate that waist circumference (WC) provides a reasonable indicator of the quantity of abdominal fat, which correlates with the amount of intra-abdominal of visceral fat [4]. An increased WC (men > 102 cm, women > 88 cm) can be a marker for increased risk even in persons with normal BMI [5]. The results from a large Dutch study showed that the associations of BMI and WC with CVD risk were equally strong [6].

(Changes in) prevalence of overweight and obesity in The Netherlands

The prevalence of overweight and obesity is increasing worldwide in both developed and developing countries [1]. According to projections of the WHO globally approximately 1.6 billion adults (age 15+) were overweight and at least 400 million adults were obese in 2005. The WHO expect that these prevalences have raised to respectively 2.3 billion and more than 700 million in 2015 [7]. Nowadays in the Netherlands the prevalence of overweight is 41% for men and 30% for women, and almost 11% is obese [8]. Since 1980 the prevalences were doubled (Figure 1) and this upward trend was similar across sexes, age groups and degrees of urbanization [9] but since 2000 the prevalence of overweight is almost stable and the prevalence of obesity increased only marginally with 2 % (to 11%) [8]. These prevalences are based on self-reported data, possible leading to underestimations [10], but analysis in measured data – although recent data is not available – confirmed these prevalences [11, 12]. In comparison to other European countries the Netherlands is ranked within the five countries of the highest percentage of male and female inhibitors with a healthy weight [13].

Causes of overweight and obesity

Overweight and obesity are caused by a positive energy balance. The fundamental principle of the energy balance is that changes in energy stores are equal to energy intake minus energy expenditure. A positive energy balance

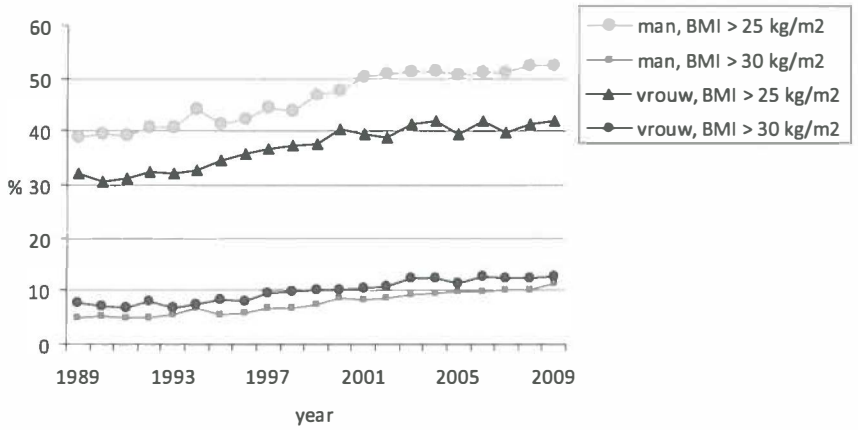


Figure 1 Trends of prevalence of overweight and obesity in the Netherlands (for persons above 20 years) between 1989 – 2009 [14]

occurs when energy intake is greater than energy expenditure; it leads to weight gain. Several factors (behaviour, environment, culture, socioeconomic, biological and genetic) are involved in the energy balance and it is the interaction between a number of these factors rather than the influence of any single factor that causes overweight and obesity [1]. The primary cause of the world wide obesity problem lies in environmental and behaviour changes [1]. With respect to intake the WHO reports an increased intake of energy-dense food that are high in fat and sugars but low in vitamins, mineral and other micronutrients and with respect to expenditure a decreased physical activity was found due to the increasingly sedentary nature of many forms of work, changing modes of transportation, and increasing urbanization [7]. The rapid raises in prevalence of overweight and obesity makes it unlikely that significant genetic changes occurred in such a short time span [1].

Consequences of overweight and obesity

Overweight and obesity are important risk factors for the development of coronary vascular diseases (partly independent of blood pressure and cholesterol levels [15]), type 2 diabetes mellitus, certain types of cancer, gastrointestinal diseases and arthritis [16, 17]. Obesity also increases the number of life years with disabilities and medication use [18, 19] and a high BMI is in itself a

strong predictor of overall mortality [20, 21]. In the Netherlands in 1999 overweight and obesity were responsible for more than 500 million euro of health care costs [22]. Besides negative outcomes on health obesity leads also to psychosocial and economic consequences [23].

Treatment on overweight and obesity

The large impact of the consequences stress the need to counteract the problem of overweight and obesity. According to (inter)national guidelines persistent lifestyle changes are necessary for preventing and managing obesity [5, 24, 25]. Numerous lifestyle interventions are developed and evaluated and several reviews showed that lifestyle interventions can achieve weight reduction [26-28]. Lifestyle interventions also decreased the risk of type 2 diabetes mellitus [29-31] and hypertension [32]. There's no clear consensus on the most (cost)-effective way for lifestyle-interventions but attention for both nutrition and physical activity, applying components from behavioural therapy, and continuity and intensity are important aspects [33-35]. In 2005, as a national strategy to tackle the obesity epidemic, a covenant was signed by ten important non health professional partners (In Dutch: Convenant Obesitas). Each of the partners, in line with their own social activity and role, had the intention to search for possibilities to contribute on achieving the aims of the government with respect to overweight in the Netherlands (In Dutch: "Preventienota Langer Gezond Leven 2004-2007").

Rationale thesis

Above mentioned lifestyle interventions showed clinically relevant reductions in body weight after one year. However, many studies included small and mainly female sample sizes and were hampered by large drop-out rates what results in poor study quality. According to the World Health Organization (WHO) additional high quality trials are needed to enlarge insight in sustained effectiveness of lifestyle counselling on body weight [1]. Further, most studies were performed in obese populations and weight regain after initial success is a commonly acknowledged problem. Therefore we developed a randomised controlled trail (GOAL – Groningen Overweight and Lifestyle – study) in a large heterogeneous population with a relatively low BMI (25-40 kg/m) and primarily focus on weight maintenance in stead of weight reduction. We aimed at weight stabilisation to prevent weight gain which was 0.05 BMI-point per year in the Netherlands between 1981 and 2004 [9]. To easily embed our intervention in the long term in regular health care we conducted our trial within the primary care setting. Previous studies have shown that lifestyle interventions in primary care can be effective at least in the short-term [36-38].

The prevalence of overweight and obesity is related to hypertension and dyslipidemia. In persons (between 18-70 years) with a BMI < 25 kg/m^2 the prevalences of these comorbidities are 23% and 13%, respectively. In persons with overweight (BMI 25-30 kg/m^2) 44% is suffering from hypertension and the prevalence of dyslipidemia is 23%. For obese persons (BMI > 30 kg/m^2) these percentages are 58% and 28%, respectively [39]. In general, efficiency of preventive cardiovascular health care need to be improved [40]. In the Netherlands, general practitioners (GP) are often responsible for the treatment of hypertension and dyslipidemia and according to their guidelines [41] this includes lifestyle advices especially in persons with a BMI > 25 kg/m^2. In this subgroup greater health gains can be achieved including achieving a healthy body weight and lifestyle changes are important to prevent them from further weight gain. Small changes in behaviour even without losing weight can improve health status [42, 43]. Lack of time and knowledge to achieve behavioural changes and insufficient continuity of care impede this approach by GP [44]. To avoid these barriers specially trained nurse practitioners (NP) are probably better equipped for lifestyle counselling than GPs [45]. The efficacy of lifestyle counselling by different health care providers is not sufficiently investigated. A Cochrane review to compare results from lifestyle counselling by dieticians and other health care providers and included just a few studies and declared that the quality from the studies was moderate [46].

Objectives of the present thesis

The main objective of this thesis was to investigate the effects of lifestyle advice by NP compared to usual care from the GP on body weight, waist circumference, blood pressure, blood parameters, physical activity and food intake. Table 1 shows the content of the GOAL intervention. Primary aim of the intervention was to achieve weight maintenance (< 1% weight gain) in the long term. Besides this we try to identify predictors of successful weight maintenance in the intervention group and to assess implementation issues and participants' opinions by performing a process evaluation in this group. To put the results from the GOAL study in a broader context we also performed a meta-analysis. In this analysis we systematically investigated the relationship between weight loss during a lifestyle intervention and the maintenance of this weight loss after an unsupervised follow-up period.

Table 1 Visits (including measurements) and contents of the lifestyle intervention for the Groningen Overweight And Lifestyle (GOAL) study

month	visit	contents	group
0	BM[a]	baseline measurement	NP, GP-UC
1	VGP1[b]	at least one visit at the GP to discuss results from baseline measurements and if necessary start treatment and control visits according the GPs guidelines	GP-UC
	V1[c]	information on healthy lifestyle, stimulating awareness of own lifestyle and body weight, extensive conversation on history of slimming and motivation to change lifestyle/lose weight and a first step in the development of the treatment plan	NP
2	V2[c]	feedback on lifestyle by criticizing food-diary, physical activity (counting steps by pedometer received in V1) and baseline questionnaires, finish treatment plan (including individual goals)	NP
3	V3[c]	evaluate the attainability of the goals and if necessary change treatment plan and if necessary refer to dietician	NP
5	F1[d]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
8	V4[c]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
12	M1[a]	measurement after 1 year	NP, GP-UC
12	VGP2[b]	at least one visit at the GP to discuss results from first year measurements and if necessary (re)start treatment and control visits according the GPs guidelines	GP-UC
	V5[c]	discuss results from measurement, evaluate and support changes on lifestyle and – if necessary – change individual goals, attention on preventing relapse to former lifestyle patterns	NP
16, 20	F2, F3[d]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
24	V6[c]	evaluate and support changes on lifestyle and – if necessary – change individual goals, attention on preventing relapse to former lifestyle patterns	NP
28, 32	F4, F5[d]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
36	M1[a]	measurement after 3 years	NP, GP-UC

[a]Measurements on e.g. body weight and height, blood pressure, serum lipids, fasting glucose, physical activity and nutrition intake
[b]VGP1-VGP2 = visit general practitioner
[c]V1-V6 = visit nurse practitioner
[d]F1-F5 = feedback moment by telephone by nurse practitioner

Definitions of "weight maintenance" and "maintenance of weight loss"
In this thesis weight maintenance, as primary aim of the GOAL intervention, is defined as less than 1% weight gain in 3 years, participants who achieved this aim are considered as successful participants. Maintenance of weight loss is also investigated, in the review it is defined as weight loss from baseline to end of the unsupervised follow-up divided by weight loss during the intervention and multiplied with 100. Maintenance of weight loss within the GOAL intervention is defined as weight loss from baseline to three years divided by weight loss from baseline to one year and multiplied with 100.

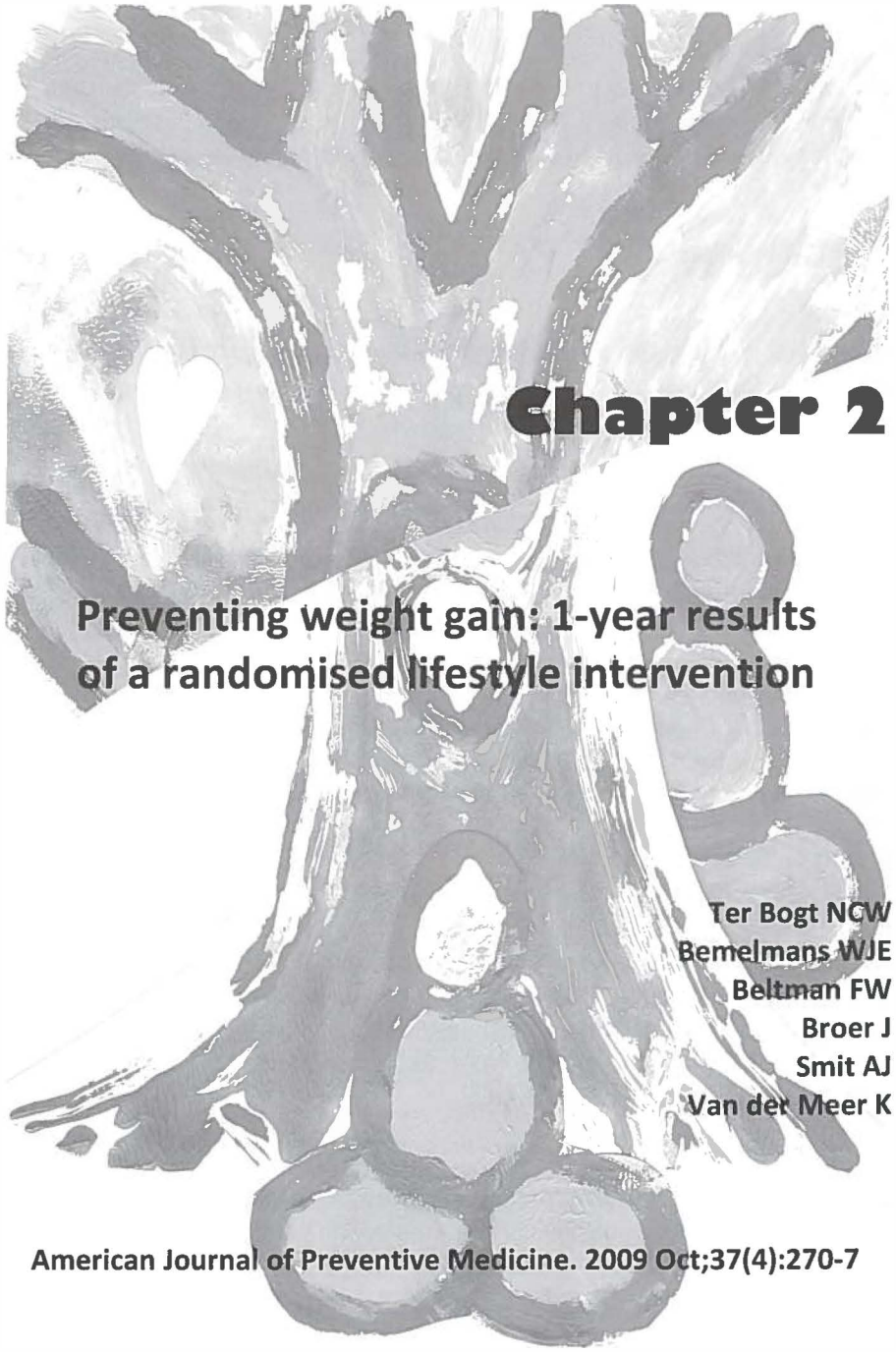
Outline of the present thesis
In *Chapter 2,* the results after 1 year lifestyle counselling by NP compared to usual care from the GP on body weight and physiological outcome variables are reported. *Chapter 3* describes the changes after 1 year in physical activity and food intake between intervention and control group. *Chapter 4* contains the results of lifestyle counselling by NP compared to usual care from the GP after 3 years on body weight and other physiological outcome values. In *Chapter 5* demographic and pre-treatment factors of weight maintenance after 3, 12 and 36 months were investigated. In *Chapter 6* the results from the process evaluation of the participants in the intervention group are presented. Besides the GOAL study the percentage of maintenance of weight loss after unsupervised follow up was investigated in a meta-analysis and reported in *Chapter 7*. Finally, *Chapter 8* is a general discussion of the overall conclusions, strengths and limitations of this study. This latter chapter also provides implications for treatment on overweight and obesity and recommendations for future research.

REFERENCES

1. WHO. *Obesity: preventing and managing the global epidemic: report of a WHO consultation.* Geneva; 2000.
2. WHO. *Physical status: the use and interpretation of anthropometry. Report of a WHO Expert Committee.*). Geneva: World Health Organization; 1995. Report Series, No. 854
3. Bjorntorp P. "Portal" adipose tissue as a generator of risk factors for cardiovascular disease and diabetes. *Arteriosclerosis.* 1990; 10(4):493-496.
4. Despres J-P, Lemieux I, Prud'homme D. Treatment of obesity: need to focus on high risk abdominally obese patients. *BMJ.* 2001; 322(7288):716-720.
5. NHLBI Obesity Initiative. *Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the evidence report.* Bethesda, MD: NIH; 1998. 98-4083.
6. van Dis LACD, Kromhout DC, Geleijnse JMC, Boer JMAB, Verschuren WMMA. Body mass index and waist circumference predict both 10-year nonfatal and fatal cardiovascular disease risk: study conducted in 20 000 Dutch men and women aged 20-65 years. *European Journal of Cardiovascular Prevention & Rehabilitation.* 2009; 16(6):729-734.
7. WHO. *Factsheet n 311. Obesity and overweight.* Geneva, 2006.
8. CBS. POLS. 2010.
9. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities in The Netherlands since 1980: stratification according to sex, age and urbanisation degree. *Int J Obes.* 2006; 31(3):515-520.
10. Gorber SC, Tremblay M, Moher D, Gorber B. A comparison of direct vs. self-report measures for assessing height, weight and body mass index: a systematic review. *Obesity Reviews.* 2007; 8(4):307-326.
11. Nooyens AC, Visscher TL, Verschuren WM, et al. Age, period and cohort effects on body weight and body mass index in adults: The Doetinchem Cohort Study. *Public Health Nutr.* 2009; 12(6):862-870.
12. Visscher TL, Kromhout D, Seidell JC. Long-term and recent time trends in the prevalence of obesity among Dutch men and women. *Int J Obes Relat Metab Disord.* 2002; 26(9):1218-1224.
13. van der Lucht F, Polder JJ (eds). *Van gezond naar beter. Volksgezondheid Toekomst Verkenning 2010.* [Towards better health. Public Health Forecast 2010] RIVM, Bilthoven, the Netherlands. Report No: 270061005.
14. www.statline.cbs.nl. Visited January 2010.
15. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: a meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med.* 2007; 167(16):1720-1728.
16. Branca F, Nikogosian H, Lobstein T. *The challenge of obesity in the WHO European Region and the strategies for response.* Copenhagen: WHO Regional Office for Europe; 2007.
17. National Task Force on the Prevention and Treatment of Obesity. Overweight, Obesity, and Health Risk. *Arch Intern Med.* 2000; 160(7):898-904.

18. Milder IE, Klungel OH, Mantel-Teeuwisse AK, Verschuren WM, Bemelmans WJ. Relation between body mass index, physical inactivity and use of prescription drugs: the Doetinchem Cohort Study. *Int J Obes (Lond). 2010;* 34(6):1060-1069.
19. Visscher TL, Rissanen A, Seidell JC, et al. Obesity and unhealthy life-years in adult Finns: an empirical approach. *Arch Intern Med. 2004;* 164(13):1413-1420.
20. Calle EE, Teras LR, Thun MJ. Obesity and Mortality. *N Engl J Med.* 2005; 353(20):2197-2199.
21. Prospective Studies C. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *The Lancet.* 2009; 373(9669):1083-1096.
22. Polder JJ TJ, Meerding WJ, Kommer GJ, Stokx LJ. *Kosten van Ziekten in Nederland. De zorgeuro ontrafelt.* Bilthoven: RIVM; 2002.
23. Wyatt SB, Winters KP, Dubbert PM. Overweight and obesity: prevalence, consequences, and causes of a growing public health problem. *Am J Med Sci.* 2006; 331(4):166-174.
24. Dutch Guideline for Healthcare Improvement (CBO). *Diagnostics and treatment of obesity in adults and children* .Utrecht, 2008.
25. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd.* 2004; 148(42):2060-2066.
26. Curioni CC, Lourenco PM. Long-term weight loss after diet and exercise: a systematic review. *Int J Obes (Lond).* 2005; 29(10):1168-1174.
27. Douketis JD, Macie C, Thabane L, Williamson DF. Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *Int J Obes (Lond).* 2005; 29(10):1153-1167.
28. Franz MJ, VanWormer JJ, Crain AL, et al. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *J Am Diet Assoc.* 2007; 107(10):1755-1767.
29. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002; 346(6):393-403.
30. Lindström J, Ilanne-Parikka P, Peltonen M, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *The Lancet.* 2006; 368(9548):1673-1679.
31. McTigue KM, Harris R, Hemphill B, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2003; 139(11):933-949.
32. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA.* 2003; 289(16):2083-2093.
33. Bemelmans WJE, Wendel-Vos GCW, Bogers RP, et al. *Kosteneffectiviteit beweeg- en dieetadvisering bij mensen met (hoog risico op) diabetes mellitus type 2. Literatuuronderzoek en modelsimulaties rondom de Beweegkuur [Cost effectiveness of exercise and healthy diet counseling among people with increased risk of type II diabetes mellitus. Literature research and model simulations concerning 'de Beweegkuur']* Bilthoven: RIVM, 2008.

34. Pi-Sunyer X. A clinical view of the obesity problem. *Science*. 2003; 299(5608):859-860.
35. Serdula MK, Khan LK, Dietz WH. Weight loss counseling revisited. *JAMA*. 2003; 289(14):1747-1750.
36. Martin PD, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. *Obesity*. 2006; 14(8):1412-1420.
37. Nanchahal K, Townsend J, Letley L, Haslam D, Wellings K, Haines A. Weight-management interventions in primary care: a pilot randomised controlled trial. *Br J Gen Pract*. 2009; 59(562):e157-166.
38. Team CP. Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. *Br J Gen Pract*. 2008; 58(553):548-554.
39. Milder IEJ, Veldwijk J, Verschuren WMM, Blokstra A, Uiters AH, Bemelmans WJE. *[Gecombineerde leefstijlbegeleiding bij overgewicht. Om hoeveel mensen gaat het in Nederland?]*. Bilthoven: RIVM; 2010.
40. Lifestyle and risk factor management and use of drug therapies in coronary patients from 15 countries; principal results from EUROASPIRE II Euro Heart Survey Programme. *Eur Heart J*. 2001; 22(7):554-572.
41. Dutch Institute for Healthcare Improvement (CBO). *Dutch Guideline Cardiovascular Risk Management*. Utrecht, 2006.
42. Laaksonen DE, Lindstrom J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes*. 2005; 54(1):158-165.
43. Powell KE, Pratt M. Physical activity and health. *BMJ*. 1996; 313(7050):126-127.
44. Hiddink GJ, Hautvast JG, Van Woerkum CM, Fieren CJ, van 't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. *Journal of Nutrition Education*. 1997; 29:36-41.
45. Lyons F. Weight management in primary care: the Counterweight Project. *J Fam Health Care*. 2005; 15(3):77-79.
46. Thompson RL, Summerbell CD, Hooper L, et al. Dietary advice given by a dietitian versus other health professional or self-help resources to reduce blood cholesterol. *Cochrane Database Syst Rev*. 2003(3):CD001366.



Chapter 2

Preventing weight gain: 1-year results of a randomised lifestyle intervention

Ter Bogt NCW
Bemelmans WJE
Beltman FW
Broer J
Smit AJ
Van der Meer K

American Journal of Preventive Medicine. 2009 Oct;37(4):270-7

ABSTRACT

Background

Lifestyle interventions targeting prevention of weight gain rather than weight loss may have better long term success than when aimed at weight loss. Limited evidence exists about such an approach in the primary care setting.

Design

An RCT was conducted

Setting/participants

457 overweight or obese patients (body mass index 25 to 40 kg/m^2; mean age 56 years; 52% female) with either hypertension and/or dyslipidemia from 11 general practice locations in The Netherlands.

Intervention

In the intervention group four individual visits to a nurse practitioner (NP) and one feedback session by telephone were scheduled for lifestyle counselling with guidance of the NP by a standardised computerized software program. The control group received usual care from their general practitioner (GP).

Main outcome measures

Changes in body weight, waist circumference, blood pressure and blood lipids after 1 year (drop-out < 10%). Data were collected in 2006 and 2007. Statistical analyses were conducted in 2007 and 2008.

Results

There were more weight losers/stabilizers in the NP group than in the GP-UC (General Practitioner Usual Care) group (77 % vs. 65%) (P<.05). In men mean weight losses were 2.3% for the NP group and 0.1% for the GP-UC group (P<.05). Significant reductions occurred also in waist circumference, but not in blood pressure, blood lipids and fasting glucose. In women mean weight losses were in both groups 1.6%. In the NP-group obese persons lost more weight (-3.0%) than non-obese (-1.3%) (P<.05).

Conclusions

Standardised computer-guided counselling by nurse practitioners may be an effective strategy to support weight gain prevention and weight loss in primary care, in our trial particularly among men.

INTRODUCTION

Like in many countries the prevalence of overweight and obesity is increasing in The Netherlands. The upward trend since 1980 is similar across sexes, age groups and degrees of urbanization [1]. Prevention of overweight is a public health priority because overweight and obesity are important risk factors for the development of coronary vascular diseases (partly independent of blood pressure and cholesterol levels [2]), type 2 diabetes mellitus, certain types of cancer, gastrointestinal diseases and arthritis [3].

According to (inter)national guidelines persistent lifestyle changes are necessary for preventing and managing obesity [4, 5]. Studies on lifestyle interventions have shown a decrease in the risk of type 2 diabetes mellitus [6-8] and hypertension [9]. Positive changes in lifestyle may improve health status even without losing weight [10]. There's no clear consensus on the most (cost)-effective way for lifestyle-interventions but attention for both nutrition and physical activity, applying components from behavioural therapy, and continuity and intensity are important aspects [11, 12].

In The Netherlands, general practitioners (GPs) are often responsible for the treatment of hypertension and dyslipidemia and according to their guidelines this treatment includes lifestyle advice. However, lack of time and knowledge to achieve behavioural changes and insufficient continuity of care impede this approach by GPs [13]. To avoid these barriers specially trained nurse practitioners (NP) are probably better equipped for lifestyle counselling than GPs [14].

Previous lifestyle interventions showed clinically relevant reductions in body weight after one year [8]. However, weight regain after initially success is a commonly acknowledge problem. Most of the studies were performed in obese populations. Further, many studies included small and mainly female sample sizes and were hampered by large drop-out rates. According to the World Health Organization (WHO) additional high quality trials are needed to enlarge insight in sustained effectiveness of lifestyle counselling on body weight [3].

To investigate the long-term effects of lifestyle counselling by NPs, and its potential contribution in counteracting the rising trend of overweight and obesity, the GOAL (Groningen Overweight And Lifestyle) study started in 2006. This randomised controlled study included over 400 overweight or obese patients at relatively 'low risk' for cardiovascular diseases. An early focus on preventing (progression of) overweight and comorbidities rather than on weight loss may be more successful in the long term. A three-year follow up for GOAL is foreseen.

The present manuscript presents the effects after 1 year follow-up of lifestyle advice by NPs (intervention condition) in comparison to care as usual by GPs (control condition) on body weight and conventional risk markers. A secondary

aim is to identify patient and study characteristics that are associated with weight loss.

METHODS

Recruitment and assignment

Initially 12 general practice locations (varying from 1 to 7 GPs and 1 to 3 NPs per location) in the Northern part of The Netherlands were willing to participate. Between June 2005 and February 2006 we invited 5738 patients (between 40 and 70 years) for a screening visit to check on inclusion criteria for the GOAL study (at random 200 to 250 patients for each GP). Almost 25% of the invited patients participated in the screening (n=1378). Presuming a BMI > 25 kg/m^2 for 50% of the GPs population [1], the response rate was almost 50% (the invitational letter discouraged patients to come if their BMI was < 24 kg/m^2). Eligible patients had to have a BMI between 25 and 40 and either hypertension or dyslipidemia or both. Hypertension was defined as mean systolic blood pressure ≥ 140 mmHg and/or diastolic ≥ 90 mmHg (based on two measurements on at least two different visits) or current use of blood pressure-lowering medication, and dyslipidemia was defined as a total serum cholesterol > 5.5 mmol/L or low HDL (male: < 0.9; female: < 1.1 mmol/L) or ratio total/HDL cholesterol > 6 and/or current use of cholesterol lowering medication. Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver- or kidney disease, current treatment for malignancy, shortened life expectancy, mentally illness and addiction to alcohol or drugs. After the screening, eligible patients received additional information about the GOAL study (n= 825) and 75% of them gave written informed consent (n=620). Between the screening and the start of the study 26% of this group dropped out, because of withdrawal of 1 general practice location from the study (n=103), changes in the Dutch health care insurance system (n=14) and patient related practical reasons (n=46) like lack of time or moving to other areas (Figure 1). The GOAL study was approved on June 2005 by the Medical Ethics Review Committee (METc) of the University Medical Center Groningen.

Baseline measurements

Between January and July 2006 baseline measurements took place and patients were allocated by computer generated random numbers to the "nurse practitioner" (NP) (n=225) or "GP usual care" (GP-UC) group (n=232) (Figure 1). A structured physical exam by a trained research team was accomplished to measure body weight, length, waist circumference and blood pressure. Body weight was measured on an electronical scale with subjects wearing light

clothing and no shoes, height was measured using a wall-mounted measuring tape, and waist circumference is measured at the level midway between the lowest rib and the iliacal crest. Blood pressure was measured twice and average values were used in analysis. The presence of cardiovascular risk factors, medication use and family history of disease and overweight/obesity were documented. Blood samples were collected after an overnight fast to analyze fasting serum lipids and glucose (in the same central laboratory, LabNoord in Groningen, using conventional and certified laboratory essays). A questionnaire, which was part of the software program for the lifestyle intervention, was completed via the internet or on paper. It contained questions on general characteristics (e.g. education level, gender) and on several issues related to body weight (e.g. history of dieting). The SQUASH-questionnaire was used to determine physical activity [15]. Metabolic syndrome was defined according to criteria from the National Cholesterol Education Program's Adult Treatment Panel III [16] and SCORE scores to estimate ten-year risk of fatal cardiovascular disease were calculated as described by Conroy *et al* [17]. Baseline data were available for all participants, with the following exceptions: waist circumference (n=2), blood analyses (n=11), complete questionnaires (n=11) and items in questionnaire (range missing items: 5-11%). These missing baseline values are distributed equally among NP and GP-UC group.

Intervention

The NPs (contracted by the GPs) followed a specially developed training program (4 sessions of 4 hours each) and received an individual instruction about the software program. The lifestyle intervention consisted of 4 individual visits and 1 feedback session by telephone in the first year. During these contact sessions the NP is guided by the standardised computerized software program which contains instructions on lifestyle counselling according to (inter)national guidelines [4, 5] and allows data entry of the measurements.

Table 1 shows the content of the visits. A process evaluation was performed with a structured questionnaire after the first three visits to investigate feasibility of the software program in daily practice. All NPs had a positive/neutral attitude about this program and the individualized lifestyle goals for patients. A large majority (75%) favoured future implementation with regular patients. Average duration of the visits was 35 minutes for the first and second visit (range 15 to 60 minutes) and 25 minutes for the third visit (range 15 to 40 minutes). The participants in the control group were offered one visit (approximately 10 minutes) with their GP to discuss results from the screening

and thereafter received usual GP care. According to national guidelines this is low intensive or absent care (regarding focus on lifestyle) for a large majority.

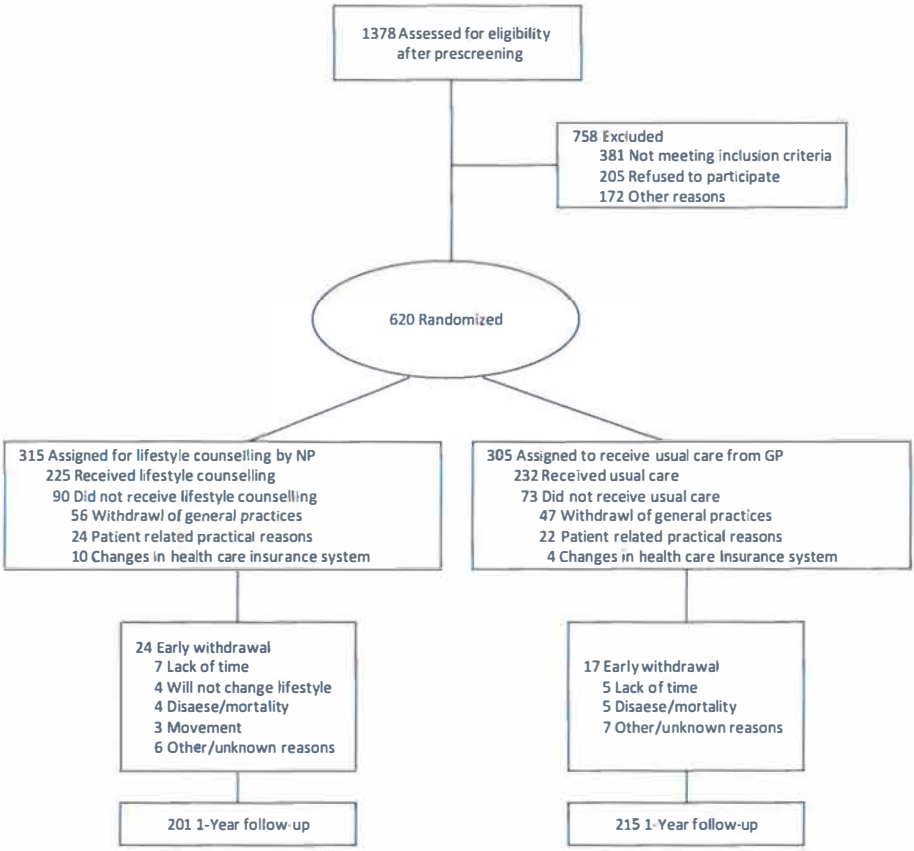


Figure 1 Flow of patients through the Groningen Overweight and Lifestyle study

Sample size calculation

Power analysis revealed that each study arm should include 145 subjects to observe (with 80% power and a 5% significance level) an expected difference in weight loss of 2.8 kg (from -0.2 kg in GP-UC group to -3.0 kg weight change in NP group) [8]. Estimating a drop-out of 15%, a minimum of 334 participants was needed to achieve 145 participants in each study arm. To allow for subgroup analyses (at least for gender) we aimed at including 667 patients.

Table 1 Visits (including measurements) and contents of the lifestyle intervention for the Groningen Overweight And Lifestyle (GOAL) study

month	visit	contents	group[a]
0	BM	baseline measurement	NP + GP-UC
1	VGP[b]	at least one visit at the GP to discuss results from baseline measurements and if necessary start treatment and control visits according the GPs guidelines	GP-UC
	V1[c]	information on healthy lifestyle, stimulating awareness of own lifestyle and body weight, extensive conversation on history of slimming and motivation to change lifestyle/lose weight and a first step in the development of the treatment plan	NP
2	V2[c]	feedback on lifestyle by criticizing food-diary, physical activity (counting steps by pedometer received in V1) and baseline questionnaires, finish treatment plan (including individual goals)	NP
3	V3[c]	evaluate the attainability of the goals and if necessary change treatment plan and if necessary refer to dietician	NP
5	F1[d]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
8	V4[c]	evaluate and support changes on lifestyle and – if necessary – change individual goals	NP
12	M1	measurement after 1 year	NP + GP-UC

[a]NP, nurse practitioner=intervention group
GP-UC, General Practitioner Usual Care=control group
[b]VGP=visit general practitioner
[c]V1-V4=visit nurse practitioner
[d]F1= feedback moment by telephone by nurse practitioner

Statistical analyses

Differences in baseline characteristics and changes in main outcome measures after one year between the two study groups were evaluated with unpaired Student's *t*-tests for continuous and Chi-Square for categorical variables. General Linear Model (GLM) was performed to adjust for baseline values. Further, GLM was used to examine the relationship between percentage weight loss after 1 year and patients' characteristics. Study group, gender and each characteristic separately were entered in the model as fixed variables and age, baseline BMI and weight change between screening and baseline as covariates. Thereafter two models were performed; the first one with significant variables from the GLM analyses and in the second model all variables were used. Multi level analysis was used to examine interaction between subjects and GP location. Differences between relevant classes within

study groups (number of visits to NP and baseline weight class) were evaluated with Student's *t*-tests for continuous and Chi-Square for categorical variables. Subjects were categorized into the following classes according to percentage of weight change after one year: successful weight losers (lost 5% or more), weight losers (weight loss from 1 to 5 %), stabilizers (between more than 1% weight loss and 1% weight gain) and weight gainers (gain more than 1%). Differences in main outcome variables between these 4 categories were tested with ANOVA and post hoc Bonferroni test.

The analyses followed the intention-to-treat principle. Results are primarily presented with exclusion of drop-outs and missing values, and adjusted for baseline values. All analyses were also performed by BOCF (baseline observation carried forward) for drop-outs. This did not alter the results except for the percentage of stabilizers/weight losers which (naturally) is higher when copying baseline values (79.1% vs. 67.2% in NP- and GP-UC group, respectively, after one year).

All analyses were performed in 2007 and 2008 using SPSS/PC statistical program version 14.0 for Windows. $P<.05$ was considered statistically significant.

RESULTS

Baseline measurements

Table 2 shows that there were no differences in the two study groups at baseline except for higher percentages having sufficient physical activity and a history of > 3 previous attempts to lose weight in the last 5 years in the GP-UC group compared to the NP-UC group. When stratified for gender, women in the GP-UC group were older (57 vs. 55 yrs), had more often hypertension (66% vs. 54%) and were more often sufficiently physically active (75% vs. 58%) ($P<.05$ for all); in men there were no significant differences in baseline values between NP and GP-UC group.

Follow-up measurement and drop-out during the first year

One year later the baseline measurements were repeated with a total of 416 persons (91%). There were no differences between these subjects and the drop-outs (n=41; 9%) for age, educational level, blood pressure and serum lipids. Drop-outs had a higher mean value of fasting glucose, higher prevalence of hypertension and lower prevalence of dyslipidemia ($P<.05$) (data not shown). Figure 1 presents reasons for drop-out.

Table 2 Baseline characteristics for nurse practitioner (NP) group and General Practitioner Usual Care (GP-UC) group

Characteristic	NP group (n=225)	GP-UC group (n=232)
General		
Age, mean (SD), y	55.3 (7.7)	56.9 (7.8)
Men, Number (%)	113 (50.2)	107 (46.1)
Low education, Number (%)	71/212 (33.5)	67/217 (30.9)
Relationship, Number (%)	177/213 (83.1)	188/226 (85.5)
Physical exam and blood analysis		
Body Mass Index, mean (SD), kg/m^2	29.5 (3.1)	29.6 (3.6)
BMI ≥ 30 kg/m^2, Number (%)	79 (35.1)	85 (36.6)
Waist circumference for men, mean (SD), cm	104 (7.8)	105 (9.5)
Waist circumference for women, mean (SD), cm	97 (9.8)	97 (11.8)
Total cholesterol, mean (SD), mmol/L	5.66 (1.0)	5.56 (1.0)
HDL-cholesterol, mean (SD), mmol/L	1.44 (0.4)	1.43 (0.4)
LDL-cholesterol, mean (SD), mmol/L	3.50 (0.9)	3.43 (0.9)
Fasting glucose, mean (SD), mmol/L	5.20 (0.5)	5.25 (0.7)
Systolic blood pressure, mean (SD), mmHg	146 (18.5)	145 (15.5)
Diastolic blood pressure, mean (SD), mmHg	87 (9.6)	86 (8.2)
Hypertension, Number (%)	137 (60.9)	145 (62.5)
Using medication for hypertension, Number (%[a])	61/136 (44.9)	74/144 (51.4)
Dyslipidemia, Number (%)	83 (36.9)	96 (41.4)
Using medication for dyslipidemia, Number (%[b])	31/83 (37.3)	43/96 (44.8)
SCORE score, mean (SD)	3.55 (4.0)	3.29 (3.0)
SCORE score < 5, Number (%)	175/219 (79.9)	182/226 (80.5)
Metabolic syndrome, Number (%)	98/224 (43.8)	102/232 (44.0)
Lifestyle		
Current smokers, Number (%)	46/224 (20.5)	42/232 (18.1)
More than 3 attempts to lose weight during last 5 years, Number (%)	33/207 (15.9)	55/213 (25.8[c])
≥ 30 minutes of moderate-intensity physical activity on 5 days / week, Number (%)	123/216 (56.9)	150/220 (68.2[c])

[a]% of participants with hypertension
[b]% of participants with dyslipidemia
[c]Chi-Square NP vs. GP-UC group $P<.05$

Changes in main outcome measures for NP and GP-UC group after one year

After 1 year there were more (successful) weight losers/stabilizers in the NP group than in the GP-UC group (77% vs. 65%) ($P<.05$). Mean weight change was -1.9% (SD 4.9) in the NP group and -0.9% (SD 5.0) in the GP-UC group ($P<.05$). Mean waist circumference decreased by 2.4 cm (SD 7.1) in the NP group and by 1.2 cm (SD 5.9) in the GP-UC group ($P=.07$). No significant differences occurred for changes in serum lipids or blood pressure.

Changes in body weight stratified for patient characteristics

Table 3 shows changes in body weight after one year stratified for patient characteristics. In the NP group, average weight loss was -2.3% for men and -1.6% for women, while in the GP-UC group women lost more weight than men (-1.6% vs. -0.1%) ($P<.05$). In the NP-group, obese participants (BMI ≥ 30 kg/m^2) and participants who visited the NP at least three times lost more body weight than participants with a lower baseline BMI (-3.0% vs. -1.3%, respectively) and those with 0-3 visits (-2.3% vs. -0.4%) ($P<.05$).

Characteristics associated with weight loss

Two GLM models were composed; the first model ($P<.001$, $R^2=0.08$) showed that weight loss is associated with study group ($P=.03$), study group X gender ($P=.03$), BMI at baseline ($P=.03$) and weight change between screening and baseline ($P<.001$) and not with gender and age. In the second model ($P<.001$, $R^2=0.12$) all variables from Table 3 were added to the first model but this didn't alter the results except for weight change between screening and baseline ($P=.06$). Multilevel analyses were performed but the variance due to general practice location was very low and not significant (intraclass correlation = .02).

Changes in main outcome variables separately for gender

The GLM model showed that gender is an effect modifier and Table 3 shows that weight loss differs according to number of NP visits and baseline weight class (obesity vs. (moderate) overweight). Table 4 therefore present changes in main outcome variables after 1-year for NP and GP-UC group, separately for men and women. For women, no significant differences were found between NP and GP-UC group although the percentage of weight losers/stabilizers tended to be higher in the NP group (73% vs. 64%, respectively; $P=.17$). For men, changes in body weight (kg and %) and waist circumference were significantly more favourable in the NP group compared to GP-UC group. The percentage of weight losers/stabilizers was higher in the NP group than in the GP-UC group (81% vs. 65%, respectively; $P<.05$).

We also performed subgroup analyses within NP group (also separately for men and women) for at least three visits versus less than three visits and for obese versus non-obese participants. For women no significant differences were found. For men changes in body weight (kg and %) and waist circumference were significantly more favourable in obese men in the NP group compared to men with a BMI smaller than 30 kg/m^2 in the NP group. Obese men in the NP group decreased more in systolic blood pressure (-14 mmHg) than obese men in the GP-UC group (-5 mmHg; $P<.05$), and in body weight (kg and %) and waist circumference ($P<.05$) (data not shown).

Table 3 Percentage change in body weight (95% CI)[a] at 1-year follow-up stratified for patients' characteristics for both study groups

	n	NP group	n	GP-UC group
Total (uncorrected)	201	-1.9 (-2.6 to -1.2)	215	-0.9 (-1.5 to -0.2)[c]
Total (adjusted)[a]	200	-1.9 (-2.5 to -1.2)	214	-0.9 (-1.5 to -0.2)[c]
Gender				
Men	97	-2.3 (-3.2 to -1.3)	100	-0.1 (-1.1 to 0.8)
Women	103	-1.6 (-2.5 to -0.6)	114	-1.6 (-2.5 to -0.7)[d]
Age				
< 60 year	141	-2.2 (-3.0 to -1.4)	127	-0.9 (-1.7 to -0.0)
≥ 60 year	59	-1.2 (-2.4 to 0.0)	87	-0.8 (-1.8 to 0.3)
Education				
Low	64	-2.5 (-3.7 to -1.3)	64	-1.2 (-2.4 to 0.0)
Other	126	-1.7 (-2.5 to -0.8)	136	-0.6 (-1.5 to 0.2)
Body Mass Index				
< 30 kg/m^2	128	-1.3 (-2.1 to -0.5)	136	-0.7 (-1.5 to 0.1)
≥ 30 kg/m^2	72	-3.0 (-4.1 to -1.9)[d]	78	-1.1 (-2.2 to 0.0)
Attempts to lose weight during last 5 years				
Never	80	-2.4 (-3.5 to -1.3)	75	-1.1 (-2.3 to 0.1)
1-3 times	73	-2.2 (-3.3 to -1.1)	70	-0.4 (-1.6 to 0.8)
More than 3 times	32	0.1 (-1.6 to 1.9)	52	-1.0 (-2.4 to 0.4)
Visits NP				
0-3 times	42	-0.4 (-1.9 to 1.0)		-
More than 3 times	158	-2.3 (-3.0 to -1.6)[d]		-
Treatment recommended[b]				
Yes	188	-2.1 (-2.7 to -1.4)	198	-0.7 (-1.4 to -0.1)
No	12	0.3 (-2.5 to 3.1)	16	-2.2 (-4.7 to 0.3)

[a]Changes are calculated as the value at 1-year follow-up minus the value at baseline and adjusted for gender, age, BMI at baseline and weight change between screening and baseline (for 1 man in the intervention group and 1 man in the control group screening data were missing)
[b]Treatment on overweight/obesity indicated according to (inter)national guidelines (motivation of patient not taken into account)
[c]*P*<.05 NP vs. GP-UC group
[d]*P*<.05 within NP or GP-UC group

Associations between outcome measures and weight changes

Except for HDL-cholesterol and fasting glucose the other outcome variables differed between the four categories of weight change, successful weight losers achieving the most favourable and weight gainers the less favourable results on outcome variables (Table 5).

Table 4 Changes[a] in main outcome measures at 1-year follow-up in NP and GP-UC group separately for women and men

	women		men	
	GP-UC group (n=114)	NP group (n=103)	GP-UC group (n=101)	NP group (n=98)
Body weight, mean (SD), kg	-1.4 (4.9)	-1.5 (4.1)	-0.0 (3.9)	-2.1 (4.8)[c]
Body weight, mean (SD), % change	-1.6 (5.6)	-1.7 (4.9)	-0.1 (4.0)	-2.1 (4.8)[c]
Waist circumference, mean (SD), cm	-1.5 (6.8)	-2.0 (7.8)	-0.9 (4.5)	-2.8 (6.2)[c]
Total cholesterol, mean (SD), mmol/L	-0.06 (0.8)	0.02 (0.8)	0.03 (0.7)	-0.18 (0.6)
HDL-cholesterol, mean (SD), mmol/L	-0.12 (0.2)	-0.11 (0.2)	-0.05 (0.2)	-0.06 (0.2)
LDL-cholesterol, mean (SD), mmol/L	0.02 (0.7)	0.15 (0.7)	0.12 (0.6)	-0.04 (0.6)
Fasting glucose, mean (SD), mmol/L	-0.11 (0.5)	-0.08 (0.6)	-0.05 (0.8)	-0.03 (0.6)
Systolic blood pressure, mean (SD), mmHg	-2.2 (16.5)	-5.3 (20.1)	-5.3 (12.7)	-8.5 (16.8)
Diastolic blood pressure, mean (SD), mmHg	0.2 (8.4)	-0.3 (9.6)	-1.3 (7.8)	-2.6 (11.2)
SCORE score, mean (SD)	0.46 (1.3)	0.10 (1.7)	-0.07 (1.3)	-0.23 (2.8)
Weight losers/stabilizers[b], Number (%)	73 (64.0)	75 (72.8)	66 (65.3)	79 (80.6)[c]

[a]Changes are calculated as the value at 1-year follow-up minus the value at baseline
[b]Percentage of subjects who gained less than 1% body weight between baseline and 1-year measurement
[c]$P<.05$ men in NP vs. men in GP-UC group after adjustment for baseline values

DISCUSSION

Lifestyle counselling using a pre-structured software program in a primary care setting succeeded in a weight reduction of 3% in the obese persons and weight maintenance in persons with moderate overweight, which is precisely according to the guidelines. The results were more favourable in men, with significant effects on waist circumference, than for women where no differences between the NP and the GP-UC groups were found. Previous research showed that clinically relevant weight loss of 5% can be achieved after one year, but that intensive programs are necessary [8]. Because of the (relatively) low intensity of the lifestyle counselling strategy, this intervention was expected to prevent weight gain or establish marginal weight loss only. In line with this expectation, for GOAL a study group was selected with low cardiovascular risk (mean SCORE score 3.4), to aim primarily at prevention of weight gain and related co-morbidities in a 'healthy population'. Nonetheless, despite this overall aim and the BMI cut-off point of 25 kg/m^2 for inclusion, in the NP group 94% has an indication for losing weight according to (inter)national guidelines on obesity (n=188) [4, 5]. In this percentage the

Table 5 Changes[a] in main outcome variables at 1-year follow-up across treatment groups, stratified for four categories of weight change

	Successful weight losers (n=79)	Weight losers (n=125)	Stabilizers (n=89)	Weight gainers (n=123)	*P* values[b]
Body weight, mean (SD), kg	-8.1 (3.9)	-2.4 (1.0)[c]	0.1 (0.4)[c]	3.3 (2.3)[c]	<.001
Body weight, mean (SD), % change	-8.9 (3.7)	-2.7 (1.1)[c]	0.1 (0.5)[c]	3.8 (2.4)[c]	<.001
Waist circumference, mean (SD), cm	-7.9 (7.1)	-2.4 (5.3)[c]	-0.6 (4.3)[c]	1.9 (5.5)[c]	<.001
Total cholesterol, mean (SD), mmol/L	-0.41 (0.9)	-0.02 (0.6)[c]	0.00 (0.7)[c]	0.12 (0.7)[c]	<.001
HDL-cholesterol, mean (SD), mmol/L	-0.05 (0.2)	-0.07 (0.2)	-0.09 (0.2)	-0.11 (0.2)	.06
LDL-cholesterol, mean (SD), mmol/L	-0.26 (0.8)	0.11 (0.5)[c]	0.10 (0.6)[c]	-0.20 (0.6)[c]	<.001
Fasting glucose, mean (SD), mmol/L	-0.19 (0.4)	-0.08 (0.5)	-0.08 (0.9)	0.03 (0.6)	.02
Systolic blood pressure, mean (SD), mmHg	-11.1 (20.2)	-8.5 (15.0)	-1.7 (13.0)[c]	-0.6 (16.9)[c]	<.001
Diastolic blood pressure, mean (SD), mmHg	-3.6 (10.1)	-2.1 (8.4)	0.2 (9.2)	1.1 (9.3)[c]	<.001

[a]Changes are calculated as the value at 1-year follow-up minus the value at baseline
[b]*P* value for linear trend
[c]*P*<.01 ANOVA with post hoc Bonferroni test with 'successful weight losers' as reference category

patient's motivation (or not) to lose weight was not taken into account. The NP discussed motivational aspects in the first visit (NP group only), and during this visit about 75% of the participants expressed a motivation for losing weight. In non-indicated and/or non-motivated patients the NP lifestyle counselling explicitly aimed at weight stabilization and - for example - no personal weight loss target was discussed, nor evaluated. The persons who had a medical indication for weight loss lost more weight after one year than the non-indicated, but this difference was not significant (Table 3). This absence of difference may be due to the fact that GOAL is a RCT and all patients gave informed consent and hereby commitment to the study. During the intervention, the average number of NP visits was almost equal in patients with counselling focused at weight loss (n=4.5) or prevention of weight increase (n=4.1). In real practice, the impact of patient's motivation and/or targeting by NP will probably be larger.

The GOAL study is a randomised controlled trial and obvious strengths are the large study population (allowing subgroup analyses) and the low drop-out rate after one year (9%). The process evaluation, using a structured questionnaire, showed that most NPs favoured future implementation. Some limitations of the GOAL study need to be discussed. There were some baseline differences between NP and GP-UC group (physical activity and attempts to lose weight) but in stratified analyses these characteristics were not related to weight change after 1 year. Second, regression to the mean may be involved since both GP-UC and NP-groups gained on average 1.0 kg between screening and baseline measurements (a period from 3 to 12 months). Weight gain during the pre-study period was significantly inversely related with weight change during the first year. However, also when evaluated from the screening on, this intervention succeeds in preventing weight gain. Regression to the mean also cannot account for the gender difference: the effect of study group was seen in men only (the difference of 2.1 kg is in line with the 2.8 kg as estimated in the power analysis; due to a smaller SD this difference was significant even with less than 145 male participants). In general, women might have more knowledge/experience on weight maintenance (for example dieting is more common in women [18] and more men than women underestimate their bodyweight [18, 19]) and a low intensive intervention may have limited extra impact in 'experienced' patients. Thirdly, randomization was done at patient level, allowing contamination of research conditions within the same GP practice. For GOAL this risk is considered quite small because there were on average (only) 40 participants per GP location (with 1 to 7 GPs per location). On the other hand, NPs were allied to GPs and they were allowed to discuss the patients' treatment with the GP. However, GPs didn't follow the special training

and could not use the software program (no license, no data available from participants). Seventeen participants from the GP-UC group were referred to the NP following usual procedures in the practice (the GP and NP didn't notice that the patients were belonging to the control group of the GOAL study). These persons didn't receive the same lifestyle counselling as the NP group because the software program could only be used for participants in the NP group. Elimination of these 17 persons didn't alter the results.

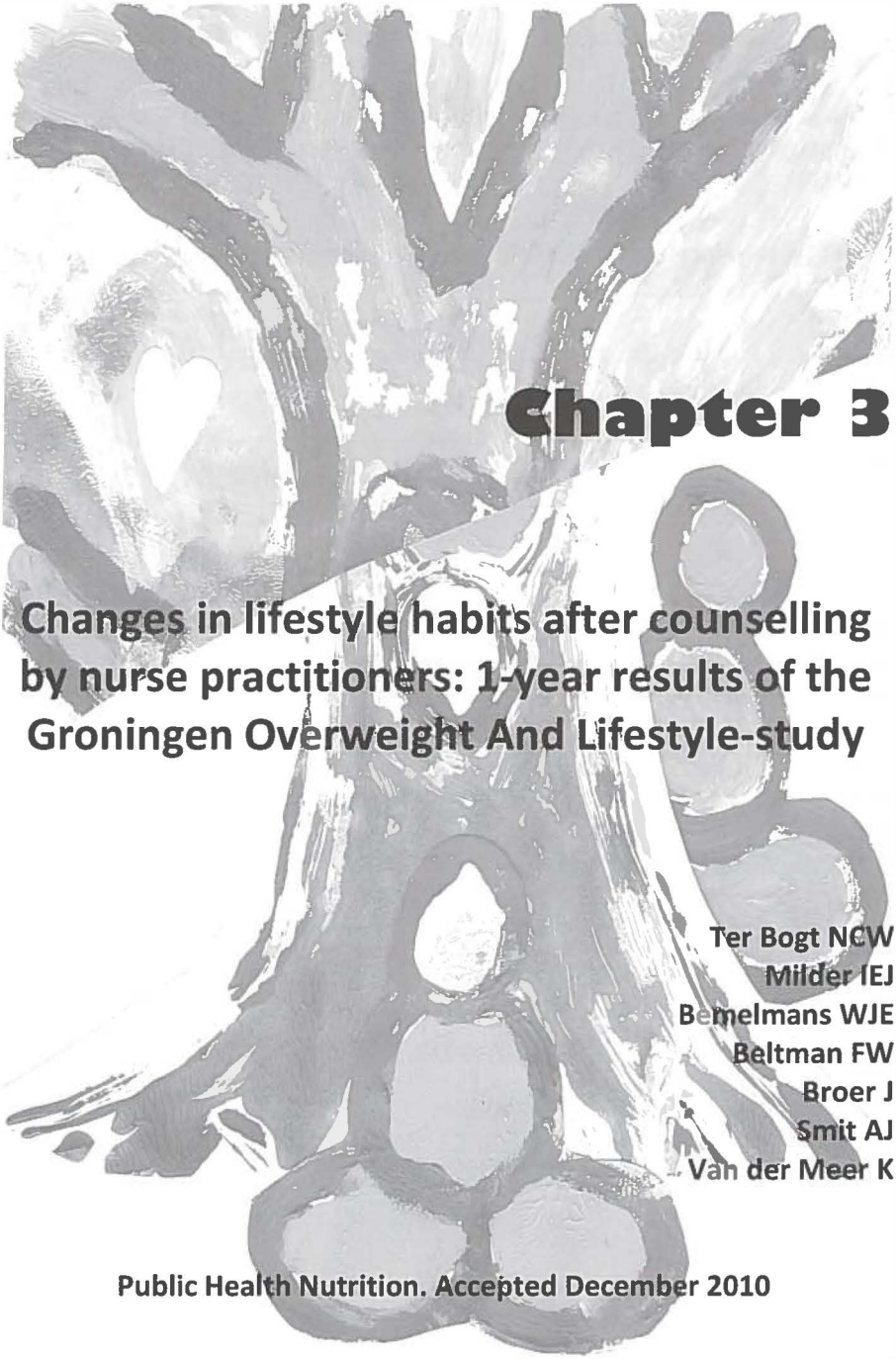
Up to now, most lifestyle interventions investigated strategies to lose weight but the first priority should be to prevent further weight gain [12, 20]. A previous low-cost intervention [21] or public health messages [22] didn't succeed in reducing weight gain with age. A recent study which compared three strategies for achieving weight maintenance after initial weight loss showed that monthly brief personal contact provided modest benefit [23]. In the GOAL study lifestyle changes are small (in congruence with a modest weight loss) which probably makes it easier not to relapse in former patterns.

Preventing overweight is a public health issue with major priority in many countries. The wider context of this study was, therefore, a 'media climate' in The Netherlands with much attention for overweight and healthy lifestyle and country wide campaigns were done in the same period. This may explain why even the control group was quite successful (65% weight losers/stabilizers). It is an important result that even against this background of other public health initiatives, lifestyle counselling in the primary health care setting is indeed of additional value. This is in line with WHO statements which acknowledges the primary health care as a key setting for overweight prevention [3]. Booth *et al* showed that GPs gave healthy lifestyle advices for obese patients rather than for those with a BMI between 23 and 30 kg/m^2 [24], while this latter group may gain more health benefits from prevention. Hence, increased awareness among GPs and measuring BMI is necessary to provide for adequate reference to NPs. The three year-results of GOAL, together with cost-effectiveness analyses, will determine if this method of lifestyle advice succeeds in sustained weight reduction/stabilization in primary care.

REFERENCES

1. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities in The Netherlands since 1980: stratification according to sex, age and urbanisation degree. *Int J Obes.* 2006; 31(3):515-520.
2. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: a meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med.* 2007; 167(16):1720-1728.
3. WHO. *The challenge of obesity in the WHO European Region and the strategies for response (eds. Branca F, Nikogosian H, Lobstein T.).* Copenhagen: WHO regional office for Europe; 2007.
4. NIH. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. 2000; Number 00-4084.
5. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd.* 2004; 148(42):2060-2066.
6. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med.* 2002; 346(6):393-403.
7. Lindström J, Ilanne-Parikka P, Peltonen M, et al. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *The Lancet.* 2006; 368(9548):1673-1679.
8. McTigue KM, Harris R, Hemphill B, et al. Screening and interventions for obesity in adults: summary of the evidence for the U.S. Preventive Services Task Force. *Ann Intern Med.* 2003; 139(11):933-949.
9. Appel LJ, Champagne CM, Harsha DW, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *JAMA.* 2003; 289(16):2083-2093.
10. Powell KE, Pratt M. Physical activity and health. *BMJ.* 1996; 313(7050):126-127.
11. Pi-Sunyer X. A clinical view of the obesity problem. *Science.* 2003; 299(5608):859-860.
12. Serdula MK, Khan LK, Dietz WH. Weight loss counseling revisited. *JAMA.* 2003; 289(14):1747-1750.
13. Hiddink GJ, Hautvast JG, Van Woerkum CM, Fieren CJ, van 't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. *Journal of Nutrition Education.* 1997; 29:36-41.
14. Lyons F. Weight management in primary care: the Counterweight Project. *J Fam Health Care.* 2005; 15(3):77-79.
15. Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol.* 2003; 56(12):1163-1169.
16. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *JAMA.* 2001; 285(19):2486-2497.
17. Conroy RM, Pyorala K, Fitzgerald AP, et al. Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. *Eur Heart J.* 2003; 24(11):987-1003.

18. Blokstra A, Burns CM, Seidell JC. Perception of weight status and dieting behaviour in Dutch men and women. *Int J Obes Relat Metab Disord.* 1999; 23(1):7-17.
19. Steenhuis IH, Bos AE, Mayer B. (Mis)interpretation of body weight in adult women and men. *J Hum Nutr Diet.* 2006; 19(3):219-228.
20. Hill JO, Thompson H, Wyatt H. Weight maintenance: what's missing? *J Am Diet Assoc.* 2005; 105(5 Suppl 1):S63-66.
21. Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. *Am J Public Health.* 1999; 89(5):747-751.
22. Williams L, Germov J, Young A. Preventing weight gain: a population cohort study of the nature and effectiveness of mid-age women's weight control practices. *Int J Obes (Lond).* 2007; 31(6):978-986.
23. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. *JAMA.* 2008; 299(10):1139-1148.
24. Booth AO, Nowson CA, Huang N, Lombard C, Singleton KL. Evaluation of a brief pilot nutrition and exercise intervention for the prevention of weight gain in general practice patients. *Public Health Nutr.* 2006; 9(8):1055-1061.



Chapter 3

Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight And Lifestyle-study

Ter Bogt NCW
Milder IEJ
Bemelmans WJE
Beltman FW
Broer J
Smit AJ
Van der Meer K

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ABSTRACT

Objectives

The GOAL (Groningen Overweight And Lifestyle) study primarily aims at preventing weight gain by nurse practitioners (NP) guided by a standardised computerized software program. Since favourable changes in physical activity (PA) and diet may improve health independently of weight (loss), insight in effects on lifestyle habits is essential. We examined the 1-year effects of lifestyle counselling by NP on PA and diet, compared with usual care from the general practitioner (GP-UC).

Design

A randomised controlled trial

Setting

Eleven general practice locations in the Netherlands

Subjects

A total of 341 GOAL participants with overweight or obesity and either hypertension or dyslipidemia, or both, who completed an FFFQ and Short QUestionnaire to ASsess Health enhancing physical activity (SQUASH) at baseline and after 1 year.

Results

After 1 year, the NP group spent 33 min/week more on walking compared with the GP-UC group who spent -5 min/week on walking (P=0.05). No significant differences were found between the NP and the GP-UC group on the percentage of persons complying with the PA guidelines. In both groups nutrient intake changed in a favourable direction and participants complied more often with dietary guidelines, but without overall difference between the NP and the GP-UC groups.

Conclusions

With the exception of an increase in walking (based on self-reported data) in the NP group, no intervention effects on PA and diet occurred. Positive changes in nutrient intake were seen in both groups.

INTRODUCTION

The prevalence of obesity is increasing worldwide and according to the World Health Organization (WHO) the (primary) health-care setting can contribute to curbing this global epidemic [1]. In a GP setting, compliance with the lifestyle component of guidelines is often limited in daily practice [2, 3]. Frequently reported barriers for lifestyle counselling by the GP, such as lack of time and insufficient knowledge, may be overcome when counselling is (partially) delegated to nurse practitioners (NP).

Previous studies have shown that lifestyle interventions in primary care can be effective at least in the short-term [4-6] and may already be (cost) effective in persons with moderate overweight (BMI 25-30 kg/m^2) [7]. In persons with at least one additional risk factor such as hypertension and/or dyslipidemia larger health gains may be achieved.

In the Groningen Overweight and Lifestyle (GOAL) study, lifestyle counselling is provided by NP, guided by a structured program incorporated into the software. The intervention aims at persistent lifestyle changes and preventing weight gain, or achieving moderate weight loss in case of motivated patients. In the intervention group, more participants achieved weight maintenance after 1 year compared with the group with usual care provided by the GP (GP-UC; control condition; 77% vs. 65%; $P<0.05$ [8]. The current paper presents the 1-year effects on diet and physical activity (PA) of software-assisted lifestyle counselling by NP compared with the control group.

METHODS

Subjects

As described elsewhere in detail [8], 457 participants from eleven general practice locations from the northern part of the Netherlands started with the intervention. Eligible participants had a BMI between 25 and 40 kg/m^2 and either hypertension or dyslipidemia, or both. Hypertension was defined as mean systolic blood pressure ≥ 140 mmHg and/or diastolic ≥ 90 mmHg (based on two measurements on at least two different visits) or current use of blood pressure-lowering medication, and dyslipidemia was defined as a total serum cholesterol > 5.5 mmol/L or low HDL (male: < 0.9; female: < 1.1 mmol/L) or ratio total/HDL cholesterol > 6 and/or current use of cholesterol-lowering medication. Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver- or kidney disease, current treatment for malignancy, severely shortened life expectancy, mental illness and addiction to alcohol or drugs. The GOAL study was approved by the Medical Ethics Review Committee of the

University Medical Center Groningen and registered by the Netherlands Trial Register (TC 1365).

Measurements

A trained research team performed a structured medical examination that included measurements of body weight, height, waist circumference and blood pressure as described elsewhere in detail [8]. Participants were asked to complete questionnaires on general characteristics (e.g., educational level, gender), PA and nutrient intake on both occasions.

Physical activity

PA was assessed using the validated Short Questionnaire to ASess Health Enhancing physical activity (SQUASH), referring to an average week in the past month [9]. Activities were classified as light, moderate, or heavy intensity based on the participants' age, the MET (metabolic equivalent) value of the activity [10] and the self-reported intensity level (slow/light, moderate, fast/intense). Complying with the National PA Guideline is defined as performing at least 30 min of moderate-to-heavy intensity activity on at least 5 d/week. Complying with the Fit Guideline is defined as performing at least 20 min of heavy intensity activities at least 3 d/wk [11].

Nutrient intake

Nutrient intake and compliance with the national dietary guidelines were assessed by a validated FFQ with the last 4 weeks as reference period [12]. Complying with guidelines on fruit and vegetables is defined as consuming at least 200g/d each; the guideline for breakfast use is defined as breakfast on at least 5 d/week. For fat intake there are two guidelines; consume maximal 10 %E saturated fat and use exclusively added fat with a favourable composition (less than 20% saturated fat).

Intervention

Patients were allocated to the NP (n=225) or to the GP-UC group (n=232) by computer generated random numbers. In the first year, the lifestyle intervention of the NP consisted of 4 individual visits (1, 2, 3 and 8 months after baseline) and 1 feedback session by telephone (5 months after baseline). During these contact sessions the NP was guided by the standardised computerized software program which contains instructions on lifestyle counselling according to (inter)national guidelines [3, 13, 14] and allows data entry of the measurements. The NP (contracted by the GP) followed a training program (4 sessions of 4 hours each) and received an individual instruction

about the software program. The primary aim was to prevent weight gain and lose 5-10% weight if patients were motivated.
The participants in the control group were offered one visit with their GP to discuss results from the screening and thereafter received usual GP care (mean number of visits was 2.0 (SD: 1.7)). According to National GP Guidelines [2] this implies low intensive or absent care (regarding focus on lifestyle) for a large majority.

Statistical analyses
Primary outcome measures are changes in dietary intake and PA 1 year after baseline. Differences in baseline characteristics and changes in outcome measures between the two study groups (also within subgroups) were evaluated with unpaired Student's *t*-tests for continuous and Chi-Square for categorical variables. A general linear model was performed to adjust for baseline values. Intervention effects for complying with dietary and PA guidelines were calculated as OR by logistic regression (adjusted for baseline values). Changes after 1 year within NP and GP-UC groups were tested with paired Student's *t* test (continuous variables) and McNemar test (categorical variables).
All analyses were performed using data of participants who completed the questionnaires. Persons who did not attend the one-year visit and/or did not complete the SQUASH and FFQ were regarded as dropouts in the analyses. Intention–to–treat analyses were performed with the baseline observation carried forward for persons for whom the one-year results were lacking.
Tests were also performed with non-parametric tests and without outliers (defined as cases outside mean +/- 2 SD) but not presented because results were similar. The total duration of PA per week was not calculated for persons with unrealistic results on the duration per day (defined as cases outside mean +/- 2 SD).
The Statistical Package for the Social Sciences statistical software package version 14.0 for Windows (SPSS Inc., Chicago, IL, USA) or the SAS statistical software package version 9.1 (SAS institute Inc, Cary, NC, USA) was used for the statistical analyses. $P<0.05$ was considered statistically significant.

RESULTS

Baseline and dropout
Baseline data on SQUASH and FFQ were available for 408 of 457 participants. After one year 67 of them did not complete both questionnaires. There were no differences in baseline nutrient intake, PA and other baseline characteristics

between dropouts and the final study group (n=341), except for energy intake. At baseline, dropouts had a lower intake of energy (7891 vs. 8576 kJ; *P*=0.011; adjusted for gender and body weight) than persons who had completed 1-year data. Table 1 shows baseline characteristics for the NP and GP-UC groups. Except for age (participants in the GP-UC were older; 57 vs. 55 year; *P*=0.026) there were no differences between these groups.

Table 1 Baseline characteristics for nurse practitioner (NP) group and General Practitioner usual care (GP-UC) group

	NP group (n=169)	GP-UC group (n=172)
Age, mean (SD), year	55.2 (7.7)	57.1 (7.7)[a]
% Men	48.5	45.3
Body Mass Index, mean (SD), kg/m^2	29.4 (3.1)	29.5 (3.7)
% BMI ≥ 30 kg/m^2	34.9	36.0
Waist circumference for men, mean (SD) cm	103.4 (7.6)	103.3 (8.5)
Waist circumference for women, mean (SD), cm	97.2 (9.6)	97.0 (12.0)
% Current smokers	21.3	14.5
% At least one attempt to lose weight during last 5 years	55.6	61.1

[a] *P*<0.05 for difference between NP and GP-UC group

Changes in PA and nutrient intake

At baseline, total and light-intensity PA in the NP group was higher compared with the GP-UC group, but moderate-to-vigorous activity and leisure-time activities did not differ between these groups (Table 2a-b).

Within the NP group, moderate-to-heavy intensity activity was significantly increased after 1 year (Table 2a-b), mainly because of increases in (leisure-time) walking and bicycling. For walking, this increase was significantly larger than in the GP-UC group. The increase in moderate-to-heavy activity in the NP group was accompanied by a decrease in light-intensity activities.

There were no significant differences in changes in nutrient intake between the NP and the GP-UC group. Both groups decreased mean daily energy intake, decreased (saturated) fat intake and increased carbohydrate, protein, vegetable and fruit intake (*P*<0.05 for all; Table 2a-b).

For 145 of 169 persons, the weight goal of the participant was recorded by the NP. A total of 113 persons had the intent to reduce their weight, and 32 persons to maintain their current weight. In the first group, 26% had ≥ 5%

weight loss, and in the second group 9% (P=0.05 for difference between groups). The mean decrease in daily energy intake in these groups was 949 and 699 kJ/d, respectively (P=0.50).

Guidelines on PA and nutrient intake
Overall, no significant intervention effects were found on the percentage of persons complying with the PA and dietary guidelines. The percentages on complying with the National PA guideline in the NP group changed from 67% to 75% compared with 73% to 70% in the GP-UC group (P=0.11). In both groups, significantly more participants complied with the guidelines on fruit and fat after 1 year (data not shown).

Intention-to-treat analyses
Intention-to-treat analyses did not alter the results substantially.

DISCUSSION

In our study, lifestyle counselling that focused on weight maintenance by NP led to an increase in walking compared with GP-UC. There were no other significant differences between groups with regard changes in PA and food intake, but both groups favourably changed nutrition behaviour.
We found a mean reduction in energy intake of 732 kJ (175 kcal)/d in both groups, which is comparable to Jeffery and French who described reductions of 368 kJ and 828 kJ (88 kcal and 198 kcal, respectively) in two intervention groups, although the counselling was not carried out individually [15]. In the Finnish Diabetes Prevention Study and PREMIER trial, higher reductions were seen in the intervention groups (1033-1343 kJ (247 –321 kcal)) but these studies aimed at weight loss in stead of weight maintenance and the results of the latter study were after 6 months [16, 17]. Light intensity activity decreased in the NP group, whereas moderate-to-heavy intensity increased, which was also found in other studies in which total time spent on PA hardly changed but activities were performed more intensively [17].
A limitation of our study may be that changes in PA and dietary behaviour were measured using questionnaires based on self-report. The use of self-reported data may have led to overestimation of PA. At baseline, a large percentage of the study population already complied with the guidelines, which may be partly explained by over-reporting because these percentages are higher than in the Dutch population [18]. Another limitation is that inviting persons to participate may have caused a selection bias resulting in a more healthy study group. However, even with these high percentages at baseline, we found a

Table 2a Changes in physical activity and food intake among intervention (NP)

	n[a]	Baseline			
		NP (n=169)		GP-UC (n=172)	
		Mean	95% CI	Mean	95% CI
Weight (kg)	169	88		87	
Total PA (min/wk)	120	2304[e]	(2095, 2513)	2026	(1867, 2185)
-Light intensity	147	1666[d]	(1496, 1836)	1368	(1221, 1516)
-Moderate-to-heavy intensity	135	596	(496, 695)	720	(616, 823)
Leisure-time physical activity	142	625	(509, 741)	656	(573, 740)
-Walking	161	174	(141, 207)	183	(154, 213)
-Bicycling	159	132	(104, 160)	135	(107, 164)
-Sports	169	160	(85, 234)	161	(114, 207)
-Gardening	164	72	(50, 93)	99	(77, 120)
-Odd jobs	156	93	(60, 126)	96	(58, 133)
Energy (kJ)	169	8587	(8182, 8993)	8566	(8182, 8949)
Energy (kcal)	169	2052	(1955, 2149)	2047	(1956, 2139)
E% fat	169	35.3	(34.4, 36.2)	34.6	(33.6, 35.5)
E% saturated fat	169	12.9	(12.5, 13.4)	12.5	(12.1, 13.0)
E% protein	169	15.4	(15.1, 15.8)	15.5	(15.1, 15.8)
E% carbohydrates	169	44.6	(43.6, 45.5)	45.3	(44.3, 46.3)
Cholesterol (mg)	169	188.6	(177.3, 200.0)	185.8	(174.3, 197.3)
Alcohol (g)	169	12.4	(10.2, 14.6)	12.7	(10.7, 14.6)
Vegetables (g)	169	145.2	(120.3, 140.7)	158.6	(125.4, 148.5)
Fruit (g)	169	130.5	(103.8, 136.4)	137.0	(109.1, 144.6)

[a] Numbers may differ due to missing items in the SQUASH questionnaire
[b] Delta's are calculated as value at 1 year measurement minus baseline value
[c] Corrected for baseline values
[d] $P<0.01$ for difference between baseline NP and GP-UC group, or for change from baseline to 1-year within group
[e] $P<0.05$ for difference between baseline NP and GP-UC group, or for change from baseline to 1-year within group

Both SQUASH and FFQ were developed to rank people according to actual nutrient intake or PA for use in epidemiological studies, and not to investigate changes over time [9, 12]. Although sensitivity of these questionnaires to measure individual changes may be limited, persons with the most positive changes in the questionnaires also reached the most positive effects on blood pressure, lipids and glucose.

Table 2b Changes in physical activity and food intake among control group (GP-UC)

	GP-UC (n=172)					
	n[a]	Baseline		Delta[b]		P value delta NP vs GP-UC[c]
		Mean	95% CI	Mean	95% CI	
Weight (kg)	172	87		-0.9[d]		0.07
Total PA (min/wk)	129	2026	(1867, 2185)	-68	(-225, 89)	0.52
-Light intensity	157	1368	(1221, 1516)	-80	(-223, 63)	0.47
-Mod.-to-heavy int	140	720	(616, 823)	-22	(-112, 68)	0.24
Leisure-time PA	146	656	(573, 740)	-14	(-85, 57)	0.31
-Walking	162	183	(154, 213)	-5	(-28, 18)	0.05
-Bicycling	160	135	(107, 164)	5	(-22, 33)	0.15
-Sports	172	161	(114, 207)	-42	(-88, 5)	0.52
-Gardening	162	99	(77, 120)	3	(-19, 25)	0.78
-Odd jobs	160	96	(58, 133)	1	(-22, 23)	0.48
Energy (kJ)	172	8566	(8182, 8949)	-733[d]	(-1029, -437)	0.97
Energy (kcal)	172	2047	(1956, 2139)	-175[d]	(-246, 105)	0.97
E% fat	172	34.6	(33.6, 35.5)	-1.9[d]	(-2.8, -1.0)	0.56
E% saturated fat	172	12.5	(12.1, 13.0)	-1.0[d]	(-1.4, -0.6)	0.16
E% protein	172	15.5	(15.1, 15.8)	0.5[d]	(0.2, 0.9)	0.68
E% carbohydrates	172	45.3	(44.3, 46.3)	1.3[d]	(0.3, 2.2)	0.43
Cholesterol (mg)	172	185.8	(174.3, 197.3)	- 21.9[d]	(-31.3, -12.4)	0.49
Alcohol (g)	172	12.7	(10.7, 14.6)	-0.6	(-2.0, 0.8)	0.44
Vegetables (g)	172	158.6	(125.4, 148.5)	13.6[e]	(1.9, 25.2)	0.87
Fruit (g)	172	137.0	(109.1, 144.6)	64.1[d]	(43.2, 84.9)	0.27

[a] Numbers may differ due to missing items in the SQUASH questionnaire
[b] Delta's are calculated as value at 1 year measurement minus baseline value
[c] Corrected for baseline values
[d] $P<0.01$ for difference between baseline NP and GP-UC group, or for change from baseline to 1-year within group
[e] $P<0.05$ for difference between baseline NP and GP-UC group, or for change from baseline to 1-year within group

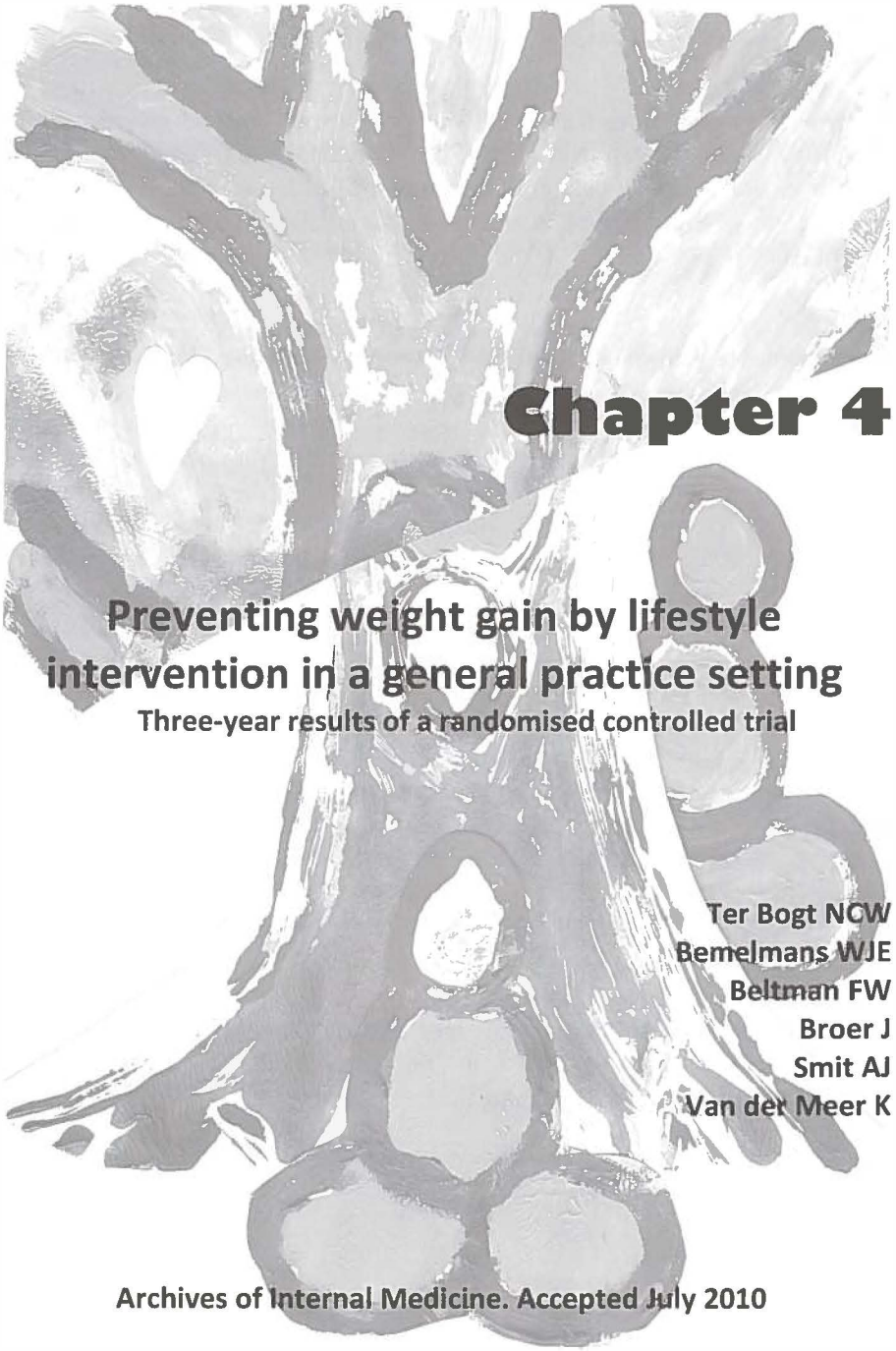
The strengths of the GOAL study are the randomised controlled design and the large study population with an equal division in gender. It is worthwhile to achieve lifestyle changes in this middle-aged, relatively low cardiovascular risk population with a moderate mean BMI to prevent weight gain and thereby prevent future accelerated increase of cardiovascular risk factors.
Despite the more intensive lifestyle counselling by NP, similar positive changes in nutrient intake were found in the GP-UC group. The countrywide campaigns

held during the course of the study for a healthy lifestyle in combination with the attention on health (and body weight) during the baseline measurements may also be responsible for changes in nutrition behaviour.
For PA, positive changes were only found in the NP group, particularly for walking and bicycling. This result is in line with one of the major aims of the intervention, which is to increase PA incorporated in daily life, rather than focus on high intensity activities such as sports, because it is expected that these changes are more sustainable in the long run. These increases in activity are valuable, because, even without changes in diet and body weight, PA can have positive health effects [22].
In conclusion, the present study shows that positive changes on nutrition behaviour can be achieved by lifestyle counselling by NP, as well as usual care. However, consistent with results on weight maintenance, positive changes on PA were only achieved by the NP. Only for walking this increase was significantly larger than in the GP-UC group.
In conclusion, this study shows that positive changes on nutrition behaviour can be achieved by lifestyle counselling by NP, as well as by GP-UC. Although an intervention effect was found on weight maintenance, there were no differences in PA and nutrition behaviour between the study groups, except for a larger increase in time spent on walking in the NP group than in the GP-UC group.

REFERENCES

1. Branca F, Nikogosian H, Lobstein T (2007) The challenge of obesity in the WHO European Region and the strategies for response. WHO Regional Office for Europe.
2. Dutch Institute for Healthcare Improvement (CBO). Dutch Guideline Cardiovascular Risk Management.Utrecht, 2006.
3. NHLBI Obesity Initiative. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the evidence report. Bethesda, MD: NIH.1998.
4. Martin PD, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. *Obesity*. 2006; 14, 1412-20.
5. Nanchahal K, Townsend J, Letley L, Haslam D, Wellings K, Haines A. Weight-management interventions in primary care: a pilot randomised controlled trial. *Br J Gen Pract*. 2009; 59, e157-66.
6. Team CP. Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. *Br J Gen Pract. 2008 ;*58, 548-54.
7. Bogers RP, Barte JCM, Schipper CMA, Vijgen SMC, de Hollander EL, Tariq L, Milder IEJ, Bemelmans WJE. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obes Rev*. 2010; 11: 51-61.
8. ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. *Am J Prev Med*. 2009; 37, 270-7.
9. Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003; 56, 1163-9.
10. Ainsworth BE, Haskell WL, Whitt MC, Irwin ML, Swartz AM, Strath SJ, *et al*. Compendium of physical activities: an update of activity codes and MET intensities. *Med Sci Sports Exerc*. 2000; 32, S498-504.
11. Kemper HCG, Ooijendijk WTM, Aggelbout M. Consensus about the Dutch physical activity guideline. *Tijdschr Soc Geneeskd*. 2000
12. Feunekes GI, Van Staveren WA, De Vries JH, Burema J, Hautvast JG. Relative and biomarker-based validity of a food-frequency questionnaire estimating intake of fats and cholesterol. *Am J Clin Nutr. 1993;* 58, 489-96.
13. NIH. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. 2000. Number 00-4084.
14. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd* .2004; 148, 2060-6.
15. Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. *Am J Public Health*. 1999; 89, 747-51.
16. Ledikwe JH, Rolls BJ, Smiciklas-Wright H, Mitchell DC, Ard JD, Champagne C, et al. Reductions in dietary energy density are associated with weight loss in overweight and obese participants in the PREMIER trial. *Am J Clin Nutr*. 2007; 85, 1212-21.
17. Lindström J, Louheranta A, Mannelin M, Rastas M, Salminen V, Eriksson J, *et al*. The Finnish Diabetes Prevention Study (DPS). *Diabetes Care*. 2003; 26, 3230-6.

18. van der Lucht F, Polder JJ (eds). Van gezond naar beter. Volksgezondheid Toekomst Verkenning 2010. [Towards better health. Public Health Forecast 2010] RIVM, Bilthoven, 2010. Report No: 270061005.
19. Molag ML, de Vries JH, Ocke MC, Dagnelie PC, van den Brandt PA, Jansen MC, et al. Design characteristics of food frequency questionnaires in relation to their validity. *Am J Epidemiol*. 2007; 166, 1468-78
20. Livingstone MBE, Black AE. Markers of the Validity of Reported Energy Intake. *J Nutr*. 2003; 133, 895S-920.
21. Black AE, Cole TJ. Biased Over- Or Under-Reporting is Characteristic of Individuals Whether Over Time or by Different Assessment Methods. *Journal of the American Dietetic Association. 2001;* 101, 70-80.
22. Laaksonen DE, Lindstrom J, Lakka TA, Eriksson JG, Niskanen L, Wikstrom K, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes*. 2005; 54, 158-65.



Chapter 4

Preventing weight gain by lifestyle intervention in a general practice setting

Three-year results of a randomised controlled trial

Ter Bogt NCW
Bemelmans WJE
Beltman FW
Broer J
Smit AJ
Van der Meer K

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ABSTRACT

Background

Weight regain after initial loss of weight is common, which indicates a need for lifestyle counselling aimed at preventing weight gain instead of weight loss. This study was conducted to determine whether structured lifestyle counselling by nurse practitioners (NP group) compared with usual care by general practitioners (GP-UC group) in overweight and obese patients can prevent weight gain.

Methods

A randomised controlled trial in 11 general practice locations in the Netherlands of 457 patients (body mass index 25 to 40 kg/m^2; mean age 56 years; 52% female) with either hypertension or dyslipidemia or both. The NP group received lifestyle counselling with guidance of the NP using a standardised software program. The GP-UC group received usual care from their GP. Main outcome measures were changes in body weight, waist circumference, blood pressure, and fasting glucose and blood lipid levels after 3 years.

Results

In both groups, approximately 60% of the participants achieved weight maintenance after 3 years. There was no significant difference in mean (SD) weight change and change of waist circumference between the NP and GP-UC groups (weight change: NP group, -1.2% (5.8), and GP-UC group, -0.6% (5.6); *P*=0.37; and change of waist circumference: NP group, -0.8 cm (7.1), and GP-UC group, 0.4 cm (7.2); *P*=0.11). A significant difference occurred for mean (SD) fasting glucose (NP group, -0.02 mmol/L (0.49), and GP-UC group, 0.10 mmol/L (0.53); *P*=0.02) but not for lipid levels and blood pressure.

Conclusions

Lifestyle counselling by NPs did not lead to significantly better prevention of weight gain compared with GPs. In the majority of both groups, lifestyle counselling succeeded in preventing (further) weight gain.

Trial Registration

Trialregister.nl Identifier: NTR1365

INTRODUCTION

The rising prevalence of overweight and obesity is a worldwide problem. An increased body mass index (BMI) is associated with higher mortality [1], the development of coronary vascular disease (partly independent of blood pressure (BP) and cholesterol levels [2]), type 2 diabetes mellitus, certain types of cancer, gastrointestinal diseases and arthritis [3]. The large impact of these diseases on shortening healthy lifespan and increasing health care costs stresses the need for strategies to tackle this problem.

Studies show that lifestyle interventions (including a nutrition and physical activity component) are needed to maintain or lose weight [4]. Intensive lifestyle programs such as Diabetes Prevention Program and Diabetes Prevention Study showed weight losses of approximately 4 kg and 3 kg, respectively, after 3 years, accompanied by improvements in cardiovascular risk factor levels [5, 6]. Because weight regain after weight loss in obese persons is a common problem, a more successful approach may be to prevent weight gain and focus on weight management in those with milder degrees of overweight. Small changes in lifestyle can improve health status even without losing weight [7, 8] and might be easier to maintain in the long term.

The primary care setting is suitable for weight maintenance; previous studies have shown that lifestyle interventions in primary care can be effective, at least in the short term [9-11]. However, little is known on long-term (over several years) effects in this setting. Guidelines in the treatment of hypertension and dyslipidemia (often accompanied by overweight and obesity) for general practitioners (GPs) include lifestyle advice, [12] but in practice, compliance with the lifestyle component of these guidelines seems limited. [13]. Frequently reported barriers for lifestyle counselling by GPs include lack of time, lack of patient compliance, insufficient knowledge about the subject, and lack of evidence-based interventions [14]. A solution to some of these barriers may be to delegate lifestyle counselling to nurse practitioners (NPs).

The Groningen Overweight and Lifestyle (GOAL) study was conducted to compare the effects of structured lifestyle counselling by NPs with usual care by general practitioners (GP-UC) on preventing weight gain and improving health status in overweight and obese patients with either hypertension, dyslipidemia, or both.

Short-term, 1-year, results of the GOAL study showed that mean weight losses in men were 2.3% in the NP group and 0.1% in the GP-UC group ($P<0.05$), while no significant reductions were found in blood lipids, fasting glucose and blood pressure. In women, weight change in both groups was -1.6%. There were more individuals with loss (weight losers) and stable weight (stabilizers) in the NP than in the GP-UC group (77% vs. 65% $P<0.05$) [15].

The present study reports the long-term, 3-year results of lifestyle counselling by NPs compared with GP-UC in overweight and obese patients at relatively 'low risk' for cardiovascular disease in preventing weight gain and improving health status. As secondary objective, we investigated whether the aforementioned 1-year results were sustained after 3 years and if weight change differed within and between subgroups.

METHODS

Subjects

Participants were recruited (between June 2005 and February 2006) at 11 general practice locations in the northern part of the Netherlands. As previously described in detail [15], after screening and selection, 457 participants (aged 40-70 years) were enrolled within a general practice setting. Eligible participants had a BMI between 25 and 40 kg/m^2 and either hypertension and/or dyslipidemia. Hypertension was defined as mean systolic BP of 140 mmHg or higher and/or diastolic BP 90 mmHg or higher (based on 2 measurements on at least 2 different visits) or current use of BP-lowering medication, and dyslipidemia was defined as a total serum cholesterol higher than 5.5 mmol/L or low HDL (male, < 0.9; female, < 1.1 mmol/L) or ratio total/HDL cholesterol greater than 6 and/or current use of cholesterol level-lowering medication. Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver- or kidney disease, current treatment for malignant disease, severely shortened life expectancy, mental illness and addiction to alcohol or drugs. The GOAL study was approved by the Medical Ethics Review Committee of the University Medical Center Groningen, Groningen, the Netherlands and written informed consent was given by all participants.

Measurements

At the GP locations, a trained research team (not blinded for study group) performed a structured medical examination that included measurements of body weight, length, waist circumference, and BP. Body weight was measured on a digital scale with subjects wearing light clothing and no shoes, height was measured using a wall-mounted measuring tape, and waist circumference was measured at the level midway between the lowest rib and the iliac crest. Blood pressure was measured twice, and mean values were used in the analysis. The presence of cardiovascular risk factors, medication use, and family history of disease and overweight/obesity were documented. Blood samples were collected in a general practice setting after an overnight fast to analyze fasting serum lipid and glucose levels (in the same central laboratory, LabNoord in

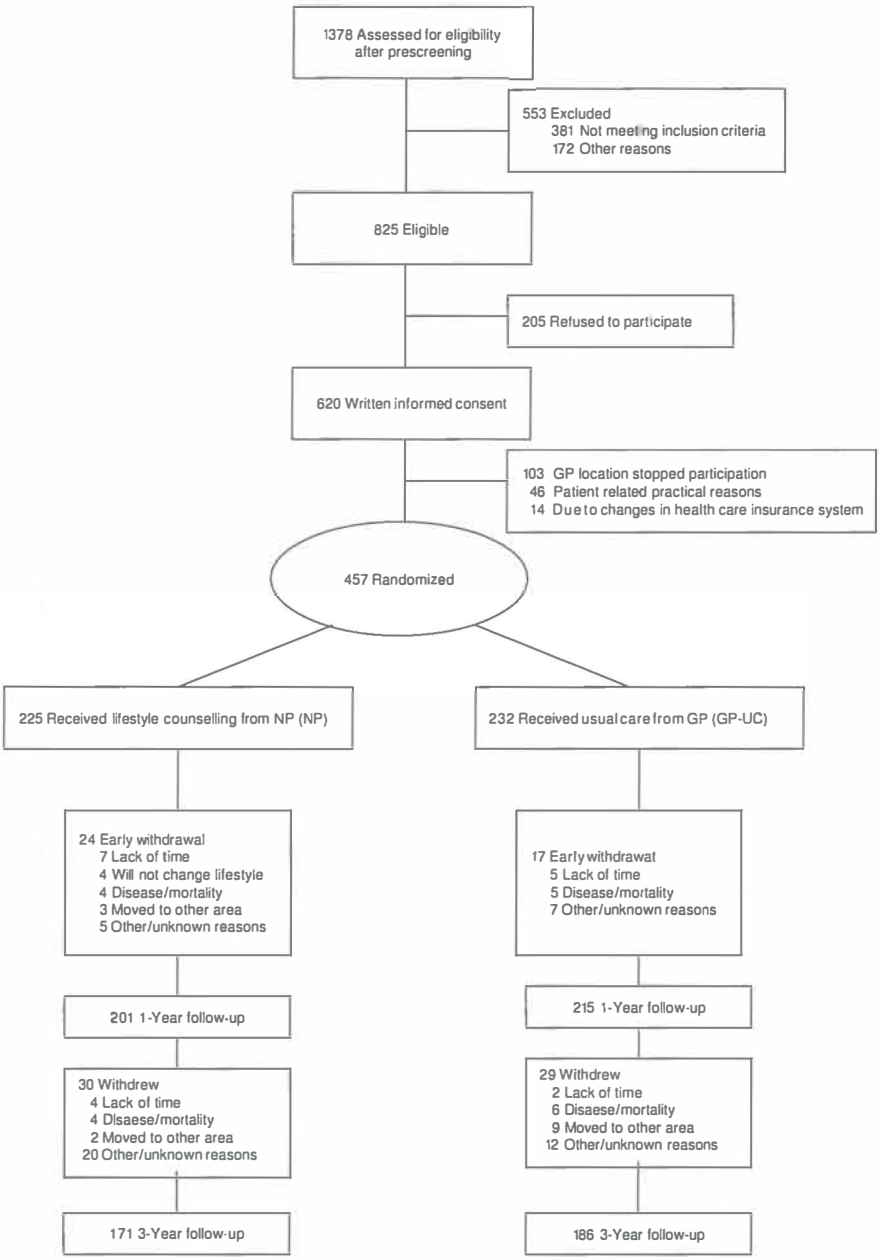

Figure 1 Flow of patients through the Groningen Overweight and Lifestyle study

Groningen, using conventional and certified laboratory assays). Several questionnaires were completed via the Internet (as part of the software program for the lifestyle intervention) or on paper (in case of no Internet access). They contained questions on general characteristics (e.g. education level and sex of the patient) and on several issues related to body weight (e.g. history of dieting). The Short Questionnaire to Assess Health enhancing physical activity (SQUASH) was used to determine physical activity [16]. Metabolic syndrome was defined according to criteria from the National Cholesterol Education Program's Adult Treatment Panel III [17] and Systematic Coronary Risk Evaluation (SCORE) scores to estimate 10-year risk of fatal cardiovascular disease were calculated as described by Conroy *et al* [18]. Baseline data were available for all participants, with the following exceptions: waist circumference (n=2), blood analyses (n=11), complete questionnaires (n=11), and items in questionnaire (range missing of items, 5-11%). These missing baseline values are distributed equally among NP and GP-UC groups. The measurements were performed at baseline (between January and July 2006), after 1 and 3 years.
The number of visits in the NP and GP-UC groups was calculated via the registration system from the general practice locations. This means that both visits within the study protocol and other visits tot the GP, NP, and practice assistant were included. Only visits that comprised lifestyle were counted (e.g. BP measurements and discussing results from blood analysis). Telephone calls and short visits were counted as 1 visit, and long visits were counted as 2 visits. The number of visits to a dietician during the study period was obtained from a separate questionnaire for the process evaluation of the study that was sent to the subjects after the 3-year measurements (50 participants did not respond to this questionnaire).

Intervention
Patients were allocated by computer generated random numbers to the NP (n=225) or GP-UC (n=232) groups. The lifestyle intervention consisted of 4 individual visits and 1 feedback session by telephone in the first year, in the next 2 years 1 individual visit and 2 feedback sessions were planned each year. During these contact sessions the NP is guided by the standardised computerized software program (exclusive use for the NP group was guaranteed), which contains instructions on lifestyle counselling according to national and international guidelines [19, 20] and allows data entry of the measurements. The NPs followed a specially developed training program (5 sessions of 4 hours each; 4 sessions before the intervention and 1 session after 1 year) and received an individual instruction about the software program before the start of the study. The program consisted of several elements of

behavioural counselling such as individual goal-setting, monitoring using food diaries and pedometers, and addressing barriers for lifestyle change. The primary aim of the intervention was to prevent weight gain and if patients were motivated to lose 5 to 10% body weight. The intervention was previously described in detail [15]. The control group visited the GP after each measurement to discuss the results, and thereafter they received usual care according to GP guidelines [12].

Sample-size calculation

The sample-size calculation was previously described in detail[15]. On the basis of previous investigations, a difference in weight loss of 2.8 kg after 1 year could be expected, resulting in the aim to include at least 145 participants in each study arm. The follow-up period in the next 2 years was meant to investigate the percentage of weight maintenance.

Statistical analyses

Differences in baseline characteristics and changes in main outcome measures after 1 and 3 years between the 2 study groups were evaluated with unpaired Student's *t*-tests for continuous and Chi-Square for categorical variables. General linear model (GLM) was performed to adjust for baseline values in continuous variables. For lipid levels and BP, adjustments were made for changes in cholesterol- and BP-lowering medications, respectively. Logistic regression, with adjustments for baseline fasting glucose level, was used to examine the relation between study group and the prevalence of impaired fasting glucose level (which is defined as a fasting glucose level > 6.0 mmol/L).
Furthermore, GLM analysis was used to examine the percentage of weight loss after 1 and 3 years in subgroups of patients. Study group, sex and each characteristic were separately entered in the model as fixed variables and age, baseline BMI, and weight change between screening and baseline as covariates. We also used GLM analysis to investigate interaction between patients' sex and study group.
Regainers were defined as subjects who lost 5% of body weight or more after 1 year and returned to baseline body weight after 3 years (≥ 0%). Subjects were categorized into the following classes according to percentage of weight change after 1 and 3 years: successful weight losers (lost ≥ 5%), weight losers (weight loss from 1% to 5%), stabilizers (between more than 1% weight loss and 1% weight gain) and weight gainers (gain ≥ 1%). Differences in main outcome variables between these categories were tested with ANOVA and post hoc Bonferroni test.

Table 1 Baseline characteristics for nurse practitioner (NP) group and usual care from general practitioner (GP-UC) group

Characteristic	NP group (n=225)	GP-UC group (n=232)
General		
Age, mean (SD), y	55.3 (7.7)	56.9 (7.8)
Men, Number (%)	113 (50.2)	107 (46.1)
Low education[a], Number (%)	71/212 (33.5)	67/217 (30.9)
Relationship[b], Number (%)	177/213 (83.1)	188/226 (85.5)
Physical exam and blood analysis		
Body weight, mean (SD), kg	88.2 (12.1)	87.8 (14.0)
Body Mass Index, mean (SD), kg/m^2	29.5 (3.1)	29.6 (3.6)
BMI ≥ 30 kg/m^2, Number (%)	79 (35.1)	85 (36.6)
Waist circumference for men, mean (SD), cm	104 (7.8)	105 (9.5)
Waist circumference for women, mean (SD), cm	97 (9.8)	97 (11.8)
Total cholesterol, mean (SD), mmol/L	5.66 (1.0)	5.56 (1.0)
HDL-cholesterol, mean (SD), mmol/L	1.44 (0.4)	1.43 (0.4)
LDL-cholesterol, mean (SD), mmol/L	3.50 (0.9)	3.43 (0.9)
Fasting glucose, mean (SD), mmol/L	5.20 (0.5)	5.25 (0.7)
Impaired fasting glucose[c], Number (%)	14/219 (6)	20/226 (9)
Systolic blood pressure, mean (SD), mmHg	146 (18.5)	145 (15.5)
Diastolic blood pressure, mean (SD), mmHg	87 (9.6)	86 (8.2)
Hypertension, Number (%)	137 (60.9)	145 (62.5)
Using medication for hypertension, Number (%[d])	61/136 (44.9)	74/144 (51.4)
Dyslipidemia, Number (%)	83 (36.9)	96 (41.4)
Using medication for dyslipidemia, Number (%[e])	31/83 (37.3)	43/96 (44.8)
SCORE score, mean (SD)	3.55 (4.0)	3.29 (3.0)
SCORE score < 5, Number (%)	175/219 (79.9)	182/226 (80.5)
Metabolic syndrome, Number (%)	98/224 (43.8)	102/232 (44.0)
Lifestyle		
Current smokers, Number (%)	46/224 (20.5)	42/232 (18.1)
More than 3 attempts to lose weight during last 5 years, Number(%)	33/207 (15.9)	55/213 (25.8[f])
≥ 30 minutes of moderate-intensity physical activity on 5 days / week, Number (%)	123/216 (56.9)	150/220 (68.2[f])

[a] % of participants with a lower professional education or less
[b] % of participants who were married or living together with a partner
[c] Fasting glucose > 6 mmol/L
[d] % of participants with hypertension
[e] % of participants with dyslipidemia
[f] Chi-Square NP vs. GP-UC group $P<.05$

Results are presented with exclusion of drop-outs and missing values, and adjusted for baseline values. Thereafter, all analyses were also performed following the intention-to-treat principle by BOCF (baseline observation carried forward) for drop outs. Usually BOCF indicates that there is no weight change

so in our study this would mean that drop outs were characterized as successful because they did not gain 1% of more of their body weight. But this might be an overestimation of the percentages of the participants who achieved weight maintenance. Therefore we also performed analyses in which all drop outs were considered as not successful which is probably an underestimation of the success rate. Percentages of participants who achieved weight maintenance are presented as a range of both methods.
All analyses were performed in 2009 using SPSS/PC statistical program version 16.0 for Windows (SPSS Inc, Chicago, Illinois). $P<0.05$ was considered statistically significant.

RESULTS

The drop out percentage was 24% for the NP and 20% for the GP-UC group ($P=0.28$) after 3 years (Figure 1). Participants who dropped out had a higher diastolic BP (89 vs. 86 mmHg; $P=0.003$) and had more often a BMI of 30 kg/m^2 or greater (reasons of drop out did not significantly differ between participants with a BMI above or under 30 kg/m^2); there were no differences in other characteristics between drop outs and participants who attended the follow-up measurement after 3 years. Table 1 gives the baseline characteristics for both groups. Participants in the GP-UC group more often had greater than 3 recent dieting attempts than in the NP group and more frequently fulfilled the norm on physical activity ($P<0.05$ for both).

Changes in main outcome measures after 3 years

After 3 years, no differences in mean (SD) weight change were present between the NP and GP-UC groups (NP, -1.2% (5.8), GP-UC: -0.6% (5.6); $P=0.37$). Approximately 60% of the participants in both groups were weight losers or stabilizers after 3 years (Table 2).
In the NP group, a positive effect was found on mean (SD) fasting glucose level at the 3-year follow-up compared with the GP-UC group (-0.02 (0.49) mmol/L vs 0.10 (0.53) mmol/L; $P=0.02$). After 3 years the prevalence of impaired fasting glucose level was 6% (n=10) in the NP group versus 12% (n=21) in the GP-UC group ($P=0.17$)) (Table 2). In persons with a BMI of 30 kg/m^2 or greater the prevalence was lower in the NP than in the GP-UC group (7% (n=4) vs. 22% (n=14) but not significant after adjustment for baseline values ($P=0.14$) (data not shown). No significant differences between the NP and GP-UC groups occurred for serum lipid levels and BP at the 3 year follow-up (Table 2).

Table 2 Changes[a] in main outcome measures at 1- and 3-year follow-up in the NP and GP-UC groups

	1-year follow up					3-year follow up				
	n	NP group	n	GP-UC group	*P*	n	NP group	n	GP-UC group	*P*
Body weight, mean (SD), kg	171	-2.0 (4.3)	186	-0.6 (4.0)	.002	171	-1.1 (5.3)	186	-0.5 (5.0)	.338
Body weight, mean (SD), % change	171	-2.2 (4.6)	186	-0.7 (4.6)	.002	171	-1.2 (5.8)	186	-0.6 (5.6)	.370
Body Mass Index, mean (SD), kg/m^2	171	-0.7 (1.4)	186	-0.2 (1.4)	.002	171	-0.4 (1.8)	186	-0.2 (1.7)	.314
Waist circumference, mean (SD), cm	169	-2.6 (7.0)	186	-1.1 (5.8)	.028	169	-0.8 (7.1)	182	0.4 (7.2)	.112
Total cholesterol, mean (SD), mmol/L	164	-0.10 (0.75)	181	-0.06 (0.71)	.498	164	0.07 (0.92)	178	-0.05 (0.93)	.147
HDL-cholesterol, mean (SD), mmol/L	164	-0.08 (0.22)	181	-0.09 (0.22)	.613	164	-0.17 (0.26)	178	-0.17 (0.25)	.752
LDL-cholesterol, mean (SD), mmol/L	162	0.04 (0.68)	179	0.05 (0.65)	.630	160	0.20 (0.81)	176	0.05 (0.86)	.086
Fasting glucose, mean (SD), mmol/L	163	-0.08 (0.48)	181	-0.06 (0.45)	.457	162	-0.02 (0.49)	176	0.10 (0.53)	.017[b]
Impaired fasting glucose[c], Number (%)	163	8 (5)	181	13 (7)	.704	162	10 (6)	176	21 (12)	.170
SBP, mean (SD), mmHg	171	-7.0 (18.6)	186	-3.3 (15.3)	.026	171	-5.9 (17.3)	186	-3.8 (14.5)	.379
DBP, mean (SD), mmHg	171	-1.5 (10.2)	186	-0.3 (8.1)	.202	171	-2.0 (10.8)	186	-1.1 (9.3)	.405
Weight losers/stabilizers[d], Number (%)	171	136 (80)	186	119 (64)	.001	171	106 (62)	186	118 (63)	.777
Regainers[e], Number (%)						37[f]	5 (14)	31[f]	5 (16)	.762

[a]Changes are calculated as the value at 1- or 3-year follow-up minus the value at baseline, and adjusted for baseline values (for lipids and blood pressure for changes in respectively cholesterol- and blood pressure-lowering medications).

[b]Adjustments for differences between the NP and the GP-UC group on baseline characteristics (physical activity and number of recent attempts to lose weight) did not alter this result

[c]Fasting glucose > 6 mmol/L, *P* values: logistic regression adjusted for baseline values

[d]Percentage of subjects who gained less than 1% body weight between baseline and 1- or 3-year measurement

[e]Percentage of subjects who lost ≥ 5% body weight after 1 year and returned to baseline body weight after 3 years (≥ 0%)

[f]Number of subjects who lost ≥ 5% body weight after 1 year

Changes in main outcome measures after 3 years compared with 1 year
Contrary to the results after 3 years, the percentage of mean (SD) weight loss after 1 year differed between the NP and GP-UC groups (NP group, -2.2% (7.0), GP-UC group, -0.7% (4.6); *P*=0.002) and there were more weight losers and stabilizers after 1 year in the NP group than in the GP-UC group (80% vs. 64%; *P*=0.001) (Table 3). The percentage of regainers in the NP group was comparable to the GP-UC group (14% and 16%, respectively) (Table 2).

Weight loss after 3 years between and within subgroups
There were no differences in weight change after 3 years between the NP and GP-UC groups in subgroups of patients' characteristics at baseline (Table 3). Interaction between sex and study group was absent. Within the NP group, participants with 3 or fewer attempts to lose weight during the last 5 years lost more weight after 3 years than participants with 4 or more attempts (*P*<0.05). These participants gained +1.4% (95% confidence interval, -0.9 to 3.7) of their baseline weight after 3 years.

Changes in main outcome variables after 3 years stratified by weight loss categories
Successful weight losers achieved the most favourable results and weight gainers the least favourable results after 3 years on physiological outcome variables except for systolic BP (Table 4). After 3 years stabilizers and weight gainers (n=192) achieved significantly better results for mean (SD) fasting glucose level (+0.10 (0.50) mmol/L) than regainers (+0.57 (0.60) mmol/L) (*P*=0.008) but not for lipid levels and BP (data not shown).

Intention-to-treat analysis
Intention-to-treat analysis did not substantially alter the results after 3 years. For example, mean (SD) weight loss after 3 years in the NP group was -0.8% (5.0) and -0.5% (5.0) in the GP-UC group (*P*=0.45). Change in mean (SD) LDL-cholesterol level did not differ between the NP and GP-UC groups (NP group, +0.15 (0.71) mmol/L, GP-UC group, +0.04 (0.77) mmol/L; *P*=0.11). Change in mean (SD) fasting glucose level after 3 years differed significantly between the NP and GP-UC groups (-0.01 (0.43) mmol/L vs. +0.08 (0.47) mmol/L; respectively, *P*=0.03). The percentages of participants who achieved weight maintenance varied from 47% to 71% in the NP group and from 51% to 71% in the GP-UC group (depending on whether dropouts are characterized as successful or not).

Table 3 Percentage change in body weight at 1- and 3-year follow-up stratified in subgroups of patients' characteristics for both study groups

	NP group % change in body weight (95% CI)[a]			GP-UC group % change in body weight (95% CI)[a]		
	n	1-year follow up	3-year follow up	n	1-year follow up	3-year follow up
Total (uncorrected)	171	-2.2 (-2.9 to -1.5)[b]	-1.2 (-2.0 to -0.3)	186	-0.7 (-1.3 to -0.0)	-0.6 (-1.4 to 0.2)
Total (adjusted)[a]	170	-2.2 (-2.9 to -1.5)[b]	-1.2 (-2.1 to -0.4)	185	-0.7 (-1.4 to -0.0)	-0.5 (-1.3 to 0.3)
Gender						
Men	84	-2.3 (-3.2 to -1.3)[b]	-1.4 (-2.6 to -0.1)	82	-0.1 (-1.1 to 0.9)	-0.2 (-1.4 to 0.9)
Women	86	-2.1 (-3.2 to -1.2)	-0.9 (-2.2 to 0.3)	103	-1.1 (-2.0 to -0.3)	-0.9 (-1.9 to 0.2)
Age						
< 60 year	117	-2.6 (-3.5 to -1.8)[b]	-0.8 (-1.9 to 0.2)	110	-0.5 (-1.4 to 0.4)	0.0 (-1.1 to 1.1)
≥ 60 year	53	-1.4 (-2.6 to -0.1)	-1.8 (-3.4 to -0.3)	75	-0.8 (-1.9 to 0.3)	-1.4 (-2.7 to -0.1)
Education						
Low	56	-3.0 (-4.3 to -1.7)	-1.2 (-2.8 to 0.3)	56	-1.2 (-2.4 to 0.1)	-0.4 (-1.9 to 1.1)
Other	106	-1.9 (-2.8 to -1.0)[b]	-1.1 (-2.3 to -0.0)	119	-0.3 (-1.1 to 0.5)	-0.7 (-1.7 to 0.3)
Body Mass Index						
< 30 kg/m^2	113	-1.7 (-2.5 to -0.8)[c]	-0.7 (-1.7 to 0.4)	121	-0.6 (-1.4 to 0.3)	-0.3 (-1.3 to 0.7)
≥ 30 kg/m^2	57	-3.3 (-4.5 to -2.1)[b]	-2.1 (-3.6 to -0.6)	64	-0.8 (-2.0 to 0.4)	-1.1 (-2.6 to 0.3)
Attempts to lose weight during last 5 year						
≤ 3 times	131	-2.6 (-3.4 to -1.8)[b,c]	-1.5 (-2.5 to -0.5)[c]	125	-0.4 (-1.3 to 0.4)	-0.5 (-1.5 to 0.5)
> 3 times	26	-0.0 (-1.9 to 1.8)	1.4 (-0.9 to 3.7)	47	-1.1 (-2.5 to 0.3)	-0.7 (-2.5 to 1.0)
Treatment recommended[d]						
Yes	159	-2.4 (-3.1 to -1.7)[b]	-1.2 (-2.1 to -0.3)	171	-0.6 (-1.3 to 0.1)	-0.5 (-1.3 to 0.3)
No	11	0.1 (-2.7 to 3.0)	0.2 (-3.3 to 3.7)	14	-1.3 (-3.8 to 1.2)	-1.3 (-4.2 to 1.7)

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Number of visits[e]						
≤ mean	108[f]	-2.3 (-3.2 to -1.4)	-1.6 (-2.7 to -0.5)	126[f]	-0.5 (-1.3 to 0.3)	-0.4 (-1.4 to 0.6)
> mean	62[f]	-2.1 (-3.3 to -0.9)	-0.5 (-1.8 to 0.9)	58[f]	-0.9 (-2.2 to 0.3)	-1.0 (-2.4 to 0.5)
Visiting a dietician						
no	116	-	-1.6 (-2.7 to -0.6)	152	-	-1.8 (-1.6 to 0.1)
yes	20	-	-0.1 (-2.5 to 2.8)	17	-	-0.4 (-3.1 to 2.3)

[a]Changes are calculated as the value at 1- or 3-year follow-up minus the value at baseline and adjusted for gender, age, BMI at baseline and weight change between screening and baseline (for 1 man in the intervention group and 1 man in the control group screening data were missing)
[b]*P*<.05 NP vs. GP-UC group, [c]*P*<.05 within NP or GP-UC group
[d]Treatment on overweight/obesity indicated according to (inter)national guidelines (motivation of patient not taken into account)
[e]Separately for the NP (mean after 1 year: 10 visits; mean after 3 years: 18 visits) and the GP-UC group (mean after 1 year: 2 visits; mean after 3 years: 4 visits)
[f]After 3 years, ≤ mean, n=100; >mean, n=70 in the NP and ≤ mean, n=123; >mean, n=61 in the GP-UC group

Table 4 Changes[a] in main outcome variables at 3-year follow-up across treatment groups, stratified by four categories of weight change

	Successful weight losers (n=71)	Weight losers (n=84)	Stabilizers (n=69)	Weight gainers (n=133)	*P* values[b]
Body weight, mean (SD), kg	-8.4 (4.5)	-2.3 (1.0)[c]	-0.1 (0.4)[c]	3.8 (2.6)[c]	<.001
Body weight, mean (SD), % change	-9.3 (4.2)	-2.7 (1.0)[c]	-0.1 (0.5)[c]	4.4 (2.9)[c]	<.001
Waist circumference, mean (SD), cm	-7.0 (8.1)	-1.2 (6.2)[c]	0.4 (4.9)[c]	3.7 (5.0)[c]	<.001
Total cholesterol, mean (SD), mmol/L	-0.23 (0.94)	0.02 (0.93)	0.05 (0.78)	0.11 (0.95)[d]	.009
HDL-cholesterol, mean (SD), mmol/L	-0.11 (0.27)	-0.17 (0.30)	-0.13 (0.23)	-0.22 (0.22)[d]	.024
LDL-cholesterol, mean (SD), mmol/L	-0.14 (0.92)	0.16 (0.85)	0.16 (0.62)	0.22 (0.87)[d]	.008
Fasting glucose, mean (SD), mmol/L	-0.11 (0.54)	-0.03 (0.46)	0.13 (0.52)[d]	0.12 (0.52)[d]	.001
Systolic blood pressure, mean (SD), mmHg	-7.3 (17.2)	-3.3 (16.5)	-7.9 (13.6)	-2.9 (15.6)	.247
Diastolic blood pressure, mean (SD), mmHg	-4.7 (10.0)	-1.2 (10.1)	-2.5 (7.9)	0.5 (10.6)[c]	.002

[a]Changes are calculated as the value at 3-year follow-up minus the value at baseline
[b]*P* value for linear trend, [c]*P*<.01 / [d]*P*<.05 ANOVA with post hoc Bonferroni test with 'successful weight losers' as reference category

DISCUSSION

The design of our study was different from several other published weight intervention studies because we focused on weight maintenance in persons with a relatively low mean BMI (almost 30 kg/m^2), and because we had a considerably longer follow up than in most other studies, within a 'realistic' primary care setting. The relevance of prolonged follow-up is reflected by the differences between the 1-year and the somewhat disappointing 3-years results on weight maintenance. After 1 year, 80% of the participants in the NP group indeed achieved weight maintenance versus 64% in the GP-UC group. However, after 3 years differences between both groups had disappeared: with 60% success in weight maintenance of the participants in both groups. Changes in fasting glucose level differed in favour of the NP group, especially among obese persons the prevalence of impaired fasting glucose differed considerably after 3 years (7% vs. 22%), but owing to lack of power in this subgroup analysis, this result was not significant when adjusted for baseline values (P=0.14).

In comparison with other studies with prolonged follow-up, Jeffery *et al*[21] described a weight gain of approximately 1.5 kg after 3 years for treatment and control groups, but they used a low-intensity intervention mostly conducted by mail. Another randomised controlled trial with a longer follow-up of 54 months was reported by Simkin-Silverman et al, [22] but this was done in postmenopausal women, with normal weight and cardiovascular risk and showed that weight maintenance is possible with a lifestyle intervention. It is notable that we found a small difference in fasting glucose level, while in the Diabetes Prevention Study, differences between intervention and control group were absent for fasting glucose level although significant differences in weight change did occur [6]. Other studies have shown that changes in lifestyle without losing weight can improve health status [7, 8].

Most of the participants in both groups achieved weight maintenance. Several factors may be responsible for the long-term lack of difference that we expected between the NP and GP groups. Patients in the GP-UC group may be more adherent to advice given by the GP because of the study circumstances. In line with the ethical committee demands, all patients were fully informed about the study purpose, and hence they knew beforehand that body weight was assessed as well as adherence to lifestyle advices. This in itself may, through some kind of Hawthorne effect, lead to modified behaviour so that all patients were more adherent than they might have been under other circumstances, and this may have diluted any differences between the groups. Moreover, both groups are also by definition as volunteers for this trial a selection of motivated patients.

The attention on health (and body weight) during the measurements in combination with abundant countrywide campaigns for a healthy lifestyle held during the course of the study may besides the visits to the GP also have been responsible for lifestyle changes in the control group. In comparison to the Dutch population where an average increase in BMI of 0.05 kg/m^2 per year (between 1981 and 2004) was described by Gast *et al* [23] we found a decrease of -0.4 kg/m^2 in the NP group and -0.2 kg/m^2 in the GP-UC group. Thus, we can consider that the majority in the NP and GP-UC groups succeeded in preventing (further) weight gain.

Besides the limitations like baseline differences between NP en GP-UC groups and randomization at patient level in stead of at practice level, as previously described in detail[15], another limitation of the GOAL study needs to be discussed. The visits to the NP after the first year occurred at a low frequency and may not be sufficient to sustained weight loss. Overall, in both groups, achieving weight maintenance was not influenced by the mean number of visits (Table 3). In the Diabetes Prevention Study 4 face-to-face visits each year were scheduled after the first year to achieve sustained weight loss after 3 years [6]. Bogers et al[24] also described that higher intervention costs (indicative for the intensity of an intervention) are associated with greater weight loss. Although this association with weight loss was determined after 1 year it is plausible that it will also apply for long-term weight loss.

In intention-to-treat analysis regarding weight change, we chose a conservative way to deal with the drop outs by carrying the baseline observation forward. This means that we assumed that dropouts during the intervention lost no weight or regained all the weight that might be lost in the first year of the intervention and thereby possibly underestimate the weight loss of the drop outs in both groups.

Strengths of our study are the large study population with an equal amount of male and female participants, a relatively low dropout after 3 years, the prolonged follow-up, and the use of an intervention that is feasible in a primary care setting. The software program can easily be used at other locations, and the intervention is not time intensive and expensive. More research is planned to evaluate the process of the GOAL intervention, which is useful for further implementation.

Analyses in subgroups showed that within the NP group participants with 3 or fewer recent attempts to lose weight had a lower weight after 3 years compared with participants with more than 3 attempts. The latter participants' mean weight gain was +1.4% (95% confidence interval, -0.9 to 3.7). This means that our intervention is not suitable for experienced dieters.

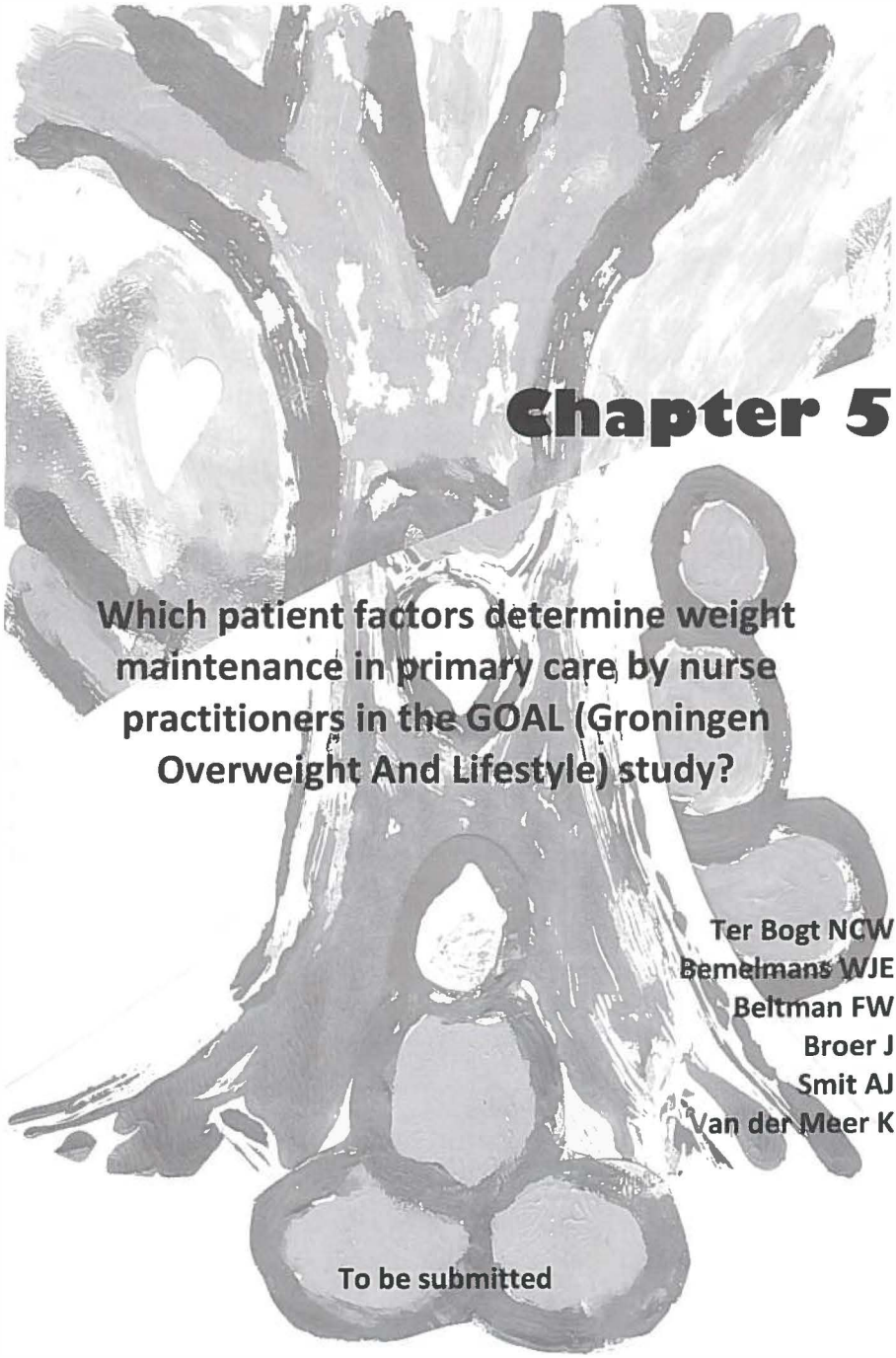
Regainers achieved unfavourable results on fasting glucose level compared with stabilizers and weight gainers, which is in line with other negative health effects of weight cycling that were described [25-27]. No clear results have been reported on the relation between repeated weight losses and mortality and the underlying mechanisms [28-31].

We can conclude that preventing (further) weight gain by NPs did not lead to significantly better results than by GPs. More follow-up sessions in the NP group may lead to a higher percentage maintenance of the weight that was lost after 1 year.

REFERENCES

1. Prospective Studies C. Body-mass index and cause-specific mortality in 900 000 adults: collaborative analyses of 57 prospective studies. *The Lancet*. 2009; 373(9669):1083-1096.
2. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: a meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med*. 2007; 167(16):1720-1728.
3. Branca F, Nikogosian H, Lobstein T. *The challenge of obesity in the WHO European Region and the strategies for response*: WHO Regional Office for Europe; 2007.
4. Wu T, Gao X, Chen M, van Dam RM. Long-term effectiveness of diet-plus-exercise interventions vs. diet-only interventions for weight loss: a meta-analysis. *Obes Rev*. 2009; 10(3):313-323.
5. Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. *N Engl J Med*. 2002; 346(6):393-403.
6. Lindström J, Louheranta A, Mannelin M, et al. The Finnish Diabetes Prevention Study (DPS). *Diabetes Care*. 2003; 26(12):3230-3236.
7. Laaksonen DE, Lindstrom J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes*. 2005; 54(1):158-165.
8. Powell KE, Pratt M. Physical activity and health. *BMJ*. 1996; 313(7050):126-127.
9. Martin PD, Rhode PC, Dutton GR, Redmann SM, Ryan DH, Brantley PJ. A primary care weight management intervention for low-income African-American women. *Obesity*. 2006; 14(8):1412-1420.
10. Nanchahal K, Townsend J, Letley L, Haslam D, Wellings K, Haines A. Weight-management interventions in primary care: a pilot randomised controlled trial. *Br J Gen Pract*. 2009; 59(562):e157-166.
11. Team CP. Evaluation of the Counterweight Programme for obesity management in primary care: a starting point for continuous improvement. *Br J Gen Pract*. Aug 2008; 58(553):548-554.
12. CBO (Dutch Institute for Healthcare Improvement). *Dutch Guideline Cardiovascular Risk Management*. Utrecht. 2006.
13. Milder IEJ, Blokstra A, de Groot J, van Dulmen S, Bemelmans WJE. Lifestyle counseling in hypertension-related visits--analysis of video-taped general practice visits. *BMC Fam Pract*. 2008; 9:58.
14. Hiddink GJ, Hautvast JG, Van Woerkum CM, Fieren CJ, van 't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. *Journal of Nutrition Education*. 1997; 29: 36-41.
15. ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. *Am J Prev Med*. 2009; 37(4):270-277.
16. Wendel-Vos GC, Schuit AJ, Saris WH, Kromhout D. Reproducibility and relative validity of the short questionnaire to assess health-enhancing physical activity. *J Clin Epidemiol*. 2003; 56(12):1163-1169.

17. Executive Summary of The Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, And Treatment of High Blood Cholesterol In Adults (Adult Treatment Panel III). *JAMA*. 2001; 285(19):2486-2497.
18. Conroy RM, Pyorala K, Fitzgerald AP, et al. Estimation of ten-year risk of fatal cardiovascular disease in Europe: the SCORE project. *Eur Heart J*. 2003; 24(11):987-1003.
19. NIH. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. 2000;Number 00-4084.
20. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd*. 2004; 148(42):2060-2066.
21. Jeffery RW, French SA. Preventing weight gain in adults: the pound of prevention study. *Am J Public Health*. 1999; 89(5):747-751.
22. Simkin-Silverman LR, Wing RR, Boraz MA, Kuller LH. Lifestyle Intervention Can Prevent Weight Gain During Menopause: Results From a 5-Year Randomized Clinical Trial. *Annals of Behavioral Medicine*. 2003; 26(3):212-220
23. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities in The Netherlands since 1980: stratification according to sex, age and urbanisation degree. *Int J Obes*. 2006; 31(3):515-520.
24. Bogers R, Barte JCM, Schipper CMA, Vijgen SMC, de Hollander EL, Tariq L, Milder IEJ, Bemelmans WJE. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obes Rev*. 2010; 11: 51-61.
25. Hamm P, Shekelle RB, Stamler J. Large fluctuations in body weight during young adulthood and twenty-five-year risk of coronary death in men. *Am J Epidemiol*. 1989; 129(2):312-318.
26. Lissner L, Odell PM, D'Agostino RB, et al. Variability of body weight and health outcomes in the Framingham population. *N Engl J Med*. 1991; 324(26):1839-1844.
27. Olson MB, Kelsey SF, Bittner V, et al. Weight cycling and high-density lipoprotein cholesterol in women: evidence of an adverse effect : A report from the NHLBI-sponsored WISE study. *Journal of the American College of Cardiology*. 2000; 36(5):1565-1571.
28. Brownell KD, Rodin J. Medical, metabolic, and psychological effects of weight cycling. *Arch Intern Med*. 1994; 154(12):1325-1330.
29. Field AE, Malspeis S, Willett WC. Weight cycling and mortality among middle-aged or older women. *Arch Intern Med*. 2009; 169(9):881-886.
30. Jeffery RW. Does weight cycling present a health risk? *Am J Clin Nutr*. 1996; 63(3 Suppl):452S-455S.
31. Rzehak P, Meisinger C, Woelke G, Brasche S, Strube G, Heinrich J. Weight change, weight cycling and mortality in the ERFORT Male Cohort Study. *Eur J Epidemiol*. 2007; 22(10):665-673.



Chapter 5

Which patient factors determine weight maintenance in primary care by nurse practitioners in the GOAL (Groningen Overweight And Lifestyle) study?

Ter Bogt NCW
Bemelmans WJE
Beltman FW
Broer J
Smit AJ
Van der Meer K

To be submitted

ABSTRACT

Objective

To assess which demographic characteristics and pre-treatment factors predict successful weight maintenance and initial (3 months), short (12 months) and long term (36 months) weight change.

Subjects

225 participants with a body mass index between 25 and 40 kg/m^2 with either hypertension or dyslipidemia, or both (age: 55.3 ± 7.8 years; female: 50%). N=147 completed all measurements.

Design

Subjects received lifestyle counselling in a primary care setting with guidance of the nurse practitioners (NP) using a standardised computerized software program.

Measurements

At baseline, after 3, 12 and 36 months BMI and questionnaire data were collected. Success was defined as weight gain < 1%.

Results

Participants who did not attempt to lose weight during the preceding five years more often achieved weight maintenance than participants with at least one attempt (12 months: respectively 89% vs. 73%; *P*=0.022, 36 months: 77% vs. 53%; *P*=0.003). Mean (CI) initial, short and long term weight changes were respectively -2.4% (-2.9 to -1.9), -2.5% (-3.2 to -1.7) and -1.6% (-2.5 to -0.7). Demographic characteristics (gender, age and educational level), motivation to lose weight and self-efficacy estimations did not independently predict weight change at any time. Motivation to increase physical activity independently explained initial weight loss only (largest in action/maintenance phase: -2.7% (CI: -3.4 to -2.0)). Strongest independent predictors of weight change were the amount of weight change between screening and baseline, baseline BMI (higher weight loss in obese persons; after 36 months : -2.4% (CI: -3.9 to -0.8) and dieting history (less weight loss in case of more than 3 recent dieting attempts before baseline; after 36 months : +1.0% (CI: -1.6 to 3.5)).

Conclusion

The GOAL type of NP guided lifestyle intervention is more successful in inexperienced dieters. Motivation did not explain success, possibly because all participants were motivated to some extent since they participated in an RCT.

INTRODUCTION

Overweight and obesity and the resulting comorbidities are increasing in many Western countries [1]. This rapid rise is due to lifestyles that result in positive energy balances. It is clear that favorable lifestyle modifications are needed to increase physical activity and to reduce energy intake. This combination is the best way of weight loss [2, 3].

Previous studies in homogeneous populations with a small number of subjects have shown that a lower level of previous dieting [4-7], higher self-efficacy [6, 8, 9] and moderate weight loss outcome evaluations [5, 6] are important predictors of successful weight loss Demographic variables like age, gender and marital status were almost never analyzed as predictors of weight loss [10]. As for gender, most studies on pre-treatment factors have been limited to (mainly) female subjects, while it is well known that gender differences on dieting behavior exist; women did more previous weight loss attempts [11-13] and have a better self-perception of their body weight than men [14, 15].

In guidelines on obesity treatment possible predictors like biological (initial body weight and resting metabolic rate) and behavioral variables (self-efficacy) are mentioned while supportive evidence is limited [16]. Besides this, no instructions exist how to address these predictors on obesity treatment. How these predictors can improve treatment and what kinds of choices are relevant for the daily practice of obesity treatment beside the relevance for health policy making and the development of new interventions. Identifying successful pre-treatment predictors for weight loss may lead to more effective strategies which can be eventually focused on specific subgroups. Adaptations in the treatment of obesity for a better prevention of diabetes and other comorbidities are highly relevant in light of the ongoing obesity epidemic.

Therefore, our aim was to assess predictors for the long term success of lifestyle advice by nurse practitioners, in the GOAL (Groningen Overweight And Lifestyle)-study which started in 2006. In comparison to other studies we had a large study population with an equal amount of male and female participants and a prolonged follow-up 36 months. Although the study primarily aimed at weight maintenance, paying attention on diet and physical activity lead through weight loss during the lifestyle intervention so we can also describe determinants of weight loss. Results show that weight maintenance was achieved for 77% of the intervention and 65% of the control group ($P< 0.05$) after 12 months [17] and in both groups for about 60% after 36 months (Arch in press). This report presents the investigation which demographic and pre-treatment factors predict successful weight maintenance and weight loss for the intervention group after 3, 12 and 36 months.

METHODS

Subjects

As elsewhere described in detail, subjects were recruited (time period between screening and baseline measurements was 3 to 12 months between in 11 general practices locations in the northern part of the Netherlands [17]. The inclusion criteria were a Body Mass Index (BMI) between 25 and 40 kg/m^2, and either hypertension and/or dyslipidemia. Hypertension was defined as mean systolic blood pressure ≥ 140 mmHg and/or diastolic ≥ 90 mmHg (based on two measurements on at least two different visits) or current use of blood pressure-lowering medication, and dyslipidemia was defined as a total serum cholesterol > 5.5 mmol/L or low HDL (male: < 0.9; female: < 1.1 mmol/L) or ratio total/HDL cholesterol > 6 and/or current use of cholesterol lowering medication for dyslipidemia. Exclusion criteria were diabetes mellitus, hypothyroidism, pregnancy, liver- or kidney disease, current treatment for malignancy, severely shortened life expectancy, mental illness and addiction to alcohol or drugs. The GOAL-study was approved by the METc of the University Medical Center Groningen. All participants received both orally and in writing information about purpose and protocol of the study and provided written informed consent before participating in the study. This report only presents data from the participants in the intervention group who started lifestyle counseling (n=225).

Intervention

The intervention of lifestyle counseling by NPs consisted of six individual visits (at month 1: ± 45 minutes; month 2: ± 40 minutes; month 3: ± 20 minutes; month 8, 12, 24: ± 15 minutes) and five feedback session by telephone (at month 5, 16, 20, 28, 32: 10 – 15 minutes) in 3 years. During these contact sessions the NP is guided by a standardized computerized software program which contains instructions on lifestyle counseling according to (inter)national guidelines [16, 18]and allows data entry of the measurements. In the first visit the participants receive information on healthy lifestyle, the NP stimulates awareness of lifestyle and body weight and discusses the history of slimming. The development of the treatment plan NP is started by exploring the participant's motivation to change lifestyle. During the second visit the participants receive feedback on their lifestyle by commenting on food-intake (by food-diary) and physical activity (counting steps by pedometer). The tailored treatment plan (including individual goals) is completed. The primary goal was to prevent weight gain or to lose 5-10% weight if patients were motivated. To reach this aim patients were stimulated to fulfil the national dietary guidelines [19], and to achieve 10 000 steps/day by pedometer. If weight

reduction was an aim, then the aims were a decrease in energy intake of 300-500 kcal/day and to achieve 10 000 - 18 000 steps/day (dependent on baseline amount of exercise and individual agreed goals). The third visit consists of evaluating the attainability of the goals, and if necessary, the treatment plan is modified. In the other contact sessions changes on lifestyle are evaluated and supported, and individual goals are adapted if necessary.

Measurements

At baseline a structured physical exam by a trained research team was accomplished to measure body weight and length, and collect additional data which are not part of the current study. Body weight was measured on a digital scale with subjects wearing light clothing and no shoes, height was measured using a wall-mounted measuring tape, and waist circumference was measured at the level midway between the lowest rib and the iliacal crest. A questionnaire which was part of the software program for the lifestyle intervention was completed via the internet or on paper. It contains questions on general characteristics (e.g. education level, gender) and on several issues related to body weight, history of slimming and motivation to change lifestyle. Motivation was measured by Stages of Change Model [20] to classify participants in precontemplation, contemplation, preparation, action and maintenance stage separately for losing weight [21]and physical activity [22]. After 12 and 36 months the above mentioned measurements were repeated. Body weight was also measured by the NP in the third visit 3 months after baseline.

Statistical analysis

Differences in baseline characteristics between subgroups (gender and BMI) were evaluated with unpaired Student's *t*-tests for continuous and Chi-Square for categorical variables. The results after 12 and 36 months were used to define two categories of success. Subjects who gained more than 1% of their baseline weight were considered as non-successful, and all other subjects were regarded as successful (because intervention was primarily focused on weight maintenance). Percentage weight maintenance after 36 months per subgroup was calculated as average percentage weight change after 36 months divided by the average percentage of weight change after 12 months and multiplied with 100. Logistic regression with forward selection was used to predict success after 12 and 36 months.

The influence of patients' characteristics on initial (3 months), short term (12 months) and long term weight loss (36 months) was evaluated by General Linear Model (GLM). Categorical variables like gender, age group (under or above 60 years), education level, BMI (under or above 30 kg/m^2), attempts to

Table 1 Baseline characteristics stratified for gender and BMI (n=225)

	men					women				
	n	< 30 kg/m^2	n	≥ 30 kg/m^2	*P* [a]	n	< 30 kg/m^2	n	≥ 30 kg/m^2	*P* [a]
Demographic characteristics										
Age (year) (SD)	79	55 (8)	34	56 (7)	0.54	67	55 (8)	45	55 (7)	0.85
Education, number low (%)	75	19 (25)	31	15 (48)	0.02	63	23 (37)	43	14 (33)	0.68
Marital status, number relationship (%)	75	66 (88)	30	26 (87)	0.85	65	52 (80)	43	33 (78)	0.69
Pre-treatment factars										
Waist circumference (cm) (SD)	78	100 (6)	33	111 (6)[e]	<0.01	67	92 (6)	45	105 (8)	<0.01
Body Mass Index (kg/m^2) (SD)	79	27 (1)[d]	34	32 (2)[e]	<0.01	67	28 (1)	45	33 (3)	<0.01
Estimation own body weight as normal, number (%)	74	26 (35)[d]	31	2 (7)	<0.01	64	12 (19)	44	2 (5)	0.03
Satisfaction own body weight, number (%)										
yes		28 (38)[d]		4 (13)			12 (19)		2 (5)	
sometimes	74	31 (42)	31	11 (36)	<0.01	63	14 (24)	44	11 (25)	0.02
no		15 (20)		16 (52)			33 (56)		31 (71)	
Attempts to lose weight during last 5 year										
never, number (%)	74	45 (61)[d]	30	15 (50)[e]	0.31	61	22 (36)	41	9 (21)	0.11
more than 5 times, number (%)	74	1 (1)[d]	30	2 (7)[e]	0.14	61	6 (10)	41	10 (24)	0.05
Stages of change losing weight, number (%)										
precontemplation		26 (37)[d]		6 (21)			12 (20)		7 (17)	
contemplation / preparation	71	20 (28)	29	8 (28)	0.22	59	14 (24)	42	13 (31)	0.70
action / maintenance		25 (35)		15 (52)			33 (56)		22 (52)	
Self-efficacy to reach ideal body weight)[b], number (%)										
(certainly) not		-		-			3 (6)		2 (5)	
don't know / no meaning	48	23 (48)	25	16 (64)	0.19	48	29 (60)	37	28 (76)	0.31
(certainly) yes		25 (52)		9 (36)			16 (33)		7 (19)	

Continues on next page

Stages of change physical activity, number (%)										
precontemplation		15 (21)		7 (25)			4 (7)		8 (18)	
contemplation / preparation	72	23 (32)	28	12 (43)	0.39	61	22 (36)	44	12 (27)	0.16
action / maintenance		34 (47)		9 (32)			35 (57)		24 (55)	
Lifestyle										
Fulfill physical activity norm[c], number (%)	77	41 (53)	31	19 (61)	0.45	64	37 (58)	44	26 (59)	0.90
Current smokers, number (%)	79	16 (20)	34	5 (15)	0.49	66	12 (18)	45	13 (29)	0.19

[a] *P* within gender

[b] % of participants with not normally estimated body weight

[c] ≥ 30 minutes of moderate-intensity physical activity in 5 days / week

[d] *P* <.05 between gender within BMI < 30 kg/m^2

[e] *P* <.05 between gender within BMI ≥ 30 kg/m^2

lose weight during last 5 year and the stages of change (losing weight and physical activity) and other variables related to body weight were separately entered in the model as fixed variables. Continuous variables like age, BMI at baseline and percentage weight change between screening and baseline were used as covariates to adjust. Thereafter we composed the best fit models to predict weight change after 3, 12 and 36 months. Significant variables from above mentioned stratified analysis were used in the models such as possible confounders like percentage weight loss between screening and baseline, BMI at baseline, gender and age.
Results are presented with exclusion of drop-outs and missing values, and adjusted for baseline values. Thereafter we repeated all analyses according the intention-to-treat principle by BOCF (baseline observation carried forward) for drop-outs. These results were not presented because this did not alter the results substantially.
All analyses were performed using SPSS/PC statistical program version 16.0 for Windows. $P < 0.05$ was considered significant.

RESULTS

Baseline characteristics intervention group

All follow up measurements were visited by 147 of 225 (65%) participants. There were no statistical differences in baseline characteristics between these participants and the participants who did not complete all follow up visits (n=78) except for treatment intention. Non-completers more often had the intention not to lose weight (34% vs. 18%; P=0.002). Table 1 shows baseline characteristics stratified for BMI and gender. Both for a BMI above and under 30 kg/m^2 more men did never an attempt to lose weight compared to women (BMI < 30 kg/m^2, men: 61%, women: 36%; P<0.001, BMI ≥ 30 kg/m^2, men: 50%, women: 21%; P=0.001). Within the BMI < 30 kg/m^2 subgroup, more male participants were satisfied with their own body weight, estimated their own body weight as normal, and were less often in action/maintenance phase on stages of change for losing weight than female participants.

Prediction of success

After 12 and 36 months, respectively, 85% and 73% of the male and 78% and 59% of the female participants achieved weight maintenance (P=0.305, P=0.093). Overall percentages, respectively, were 81% and 66%. Overall, the best model (Nagelkerke R^2=0.215) to predict success after 12 months included attempts to lose weight (B=-1.45, P=0.020), educational level (B=1.51, P=0.029) and weight change between screening and baseline (B=0.18, P=0.030). After 36

months the best model (Nagelkerke R^2=0.135) to predict success only consisted of attempts to lose weight (B=-1.45, *P*=0.001). In men after 12 months and in women after 36 months there were no variables that significantly predict weight maintenance. The best model to predict success in men after 36 months (Nagelkerke R^2=0.355) and in women after 12 months (Nagelkerke R^2=0.212) consisted of attempts to lose weight (men: B=-2.37, *P*=0.003; women: B=-2.37, *P*=0.036) and stage of change physical activity (men: B=-1.69, *P*=0.010; women: B=0.92, *P*=0.054).

Weight change stratified for demographic and pre-treatment factors

After 3 months mean weight loss was -2.4%. This was independent of demographic characteristics but differed for stage of change physical activity (lowest weight loss for the precontemplation stage: -0.6% (-1.9 to 0.7): *P*<0.05) (table 2). After 12 months mean weight loss was comparable with weight loss after 3 months and differed for age (< 60 years: -3.1 (-4.0 to -2.2), ≥ 60 years: -1.3 (-2.6 to −0.0); *P*<0.05). After 36 months weight loss after 12 months was maintained for 64% and weight loss only differed for the number of attempts to lose weight (never:-2.7% (-4.1 to -1.2), more than 3 times: 1.0% (-1.5 to 3.6); *P*<0.05).

Stratified analysis for gender showed that weight loss in men differed after 12 months for BMI (< 30 kg/m^2: -1.8 (-3.1 to 0.4), ≥ 30 kg/m^2: -4.4 (-6.3 to -2.5); *P*<0.05). In women after 12 months and in men after 36 months a trend was seen for the number of attempts to lose weight (men: (never:-3.3% (-5.2 to -1.5), more than 3 times: 2.0% (-2.8 to 6.8); *P*=0.05), women: (never:-3.4% (-5.2 to -1.5), more than 3 times: 0.4% (-2.0 to 2.7); *P*=0.05). After 36 months weight loss after 12 months was maintained for 54% in women and for 73% in men (data not shown).

General Linear Model on demographic and pre-treatment factors associated with weight change

We composed the best fit models to predict weight change after 3, 12 and 36 months. The model after 3 months (*P*=0.000, R^2=0.21) showed that initial weight change is associated with stage of change of physical activity (*P*=0.024), the number of attempts to lose weight in the last 5 year (*P*=0.041) and percentage weight change between screening and baseline (*P*=0.000). The model after 12 months (*P*=0.000, R^2=0.60) showed that short term weight change was associated with BMI at baseline (*P*=0.000), the number of attempts to lose weight in the last 5 year (*P*=0.024) and the percentage weight change between screening and baseline (*P*=0.000). The model after 36 months (*P*=0.000, R^2=0.26) showed that long term weight loss was associated with BMI

Table 2 Weight change (in % of baseline) after 3, 12 and 36 months stratified for baseline characteristics

	n	% weight change after 3 months[a]		% weight change after 12 months[a]		% weight change after 36 months[a]	
		mean	(95% CI)	mean	(95% CI)	mean	(95% CI)
Total (uncorrected)	147	-2.4	(-2.9 to -1.9)	-2.5	(-3.2 to -1.7)	-1.6	(-2.5 to -0.7)
Total[a]	146	-2.4	(-2.9 to -1.9)	-2.5	(-3.2 to -1.8)	-1.6	(-2.5 to -0.7)
Demographic characteristics							
Gender							
male	72	-2.4	(-3.1 to -1.7)	-2.8	(-3.8 to -1.7)	-2.0	(-3.3 to -0.7)
female	74	-2.4	(-3.1 to -1.8)	-2.2	(-3.3 to -1.2)	-1.2	(-2.5 to 0.1)
Age							
< 60 year	97	-2.5	(-3.1 to -2.0)	-3.1	(-4.0 to -2.2)[b]	-1.6	(-2.7 to -0.4)
≥ 60 year	49	-2.2	(-3.0 to -1.4)	-1.3	(-2.6 to -0.0)	-1.7	(-3.2 to -0.1)
Education							
low	51	-2.2	(-3.0 to -1.3)	-3.1	(-4.4 to -1.8)	-1.7	(-3.3 to -0.1)
intermediate and high	90	-2.6	(-3.2 to -2.0)	-2.2	(-3.2 to -1.3)	-1.6	(-2.8 to -0.4)
Pre-treatment factors							
BMI							
< 30 kg/m^2	94	-2.5	(-3.0 to -1.9)	-2.0	(-2.9 to -1.1)	-1.2	(-2.3 to -0.0)
≥ 30 kg/m^2	52	-2.3	(-3.1 to -1.5)	-3.4	(-4.6 to -2.1)	-2.4	(-3.9 to -0.8)
Satisfaction own body weight							
yes	29	-2.0	(-3.1 to -0.9)	-2.6	(-4.4 to -0.9)	-1.5	(-3.6 to 0.6)
sometimes	52	-2.6	(-3.4 to -1.8)	-2.5	(-3.8 to -1.3)	-1.5	(-3.1 to -0.0)
no	59	-2.5	(-3.3 to -1.7)	-2.5	(-3.7 to -1.3)	-1.8	(-3.3 to -0.3)
Attempts to lose weight during last 5 year							
never	61	-2.9	(-3.6 to -2.2)	-3.3	(-4.5 to -2.1)	-2.7	(-4.1 to -1.2)[b]
1-3 times	54	-2.4	(-3.2 to -1.7)	-2.2	(-3.5 to -1.0)	-1.1	(-2.6 to 0.4)
more than 3 times	20	-1.0	(-2.3 to 0.3)	-0.5	(-2.6 to 1.6)	1.0	(-1.5 to 3.6)

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Self-efficacy to reach ideal body weight[c]							
(certainly) not	4	-1.5	(-4.5 to 1.6)	0.4	(-5.5 to 6.3)	0.4	(-5.5 to 6.3)
don't know / no meaning	64	-2.6	(-3.3 to -1.8)	-2.4	(-3.8 to -0.9)	-2.4	(-3.8 to -0.9)
(certainly) yes	39	-2.4	(-3.4 to -1.4)	-0.6	(-2.5 to 1.3)	-0.6	(-2.5 to 1.3)
Stages of change physical activity							
precontemplation	19	-0.6	(-1.9 to 0.7)[b]	-1.5	(-3.7 to 0.6)	-2.0	(-4.7 to 0.7)
contemplation/preparation	41	-2.4	(-3.3 to -1.5)	-2.8	(-4.2 to -1.3)	-1.2	(-3.0 to 0.6)
action/maintenance	72	-2.7	(-3.4 to -2.0)	-2.7	(-3.8 to -1.6)	-1.9	(-3.2 to -0.5)
Stages of change losing weight							
precontemplation	32	-1.7	(-2.7 to -0.6)	-2.8	(-4.5 to -1.2)	-2.1	(-4.1 to -0.1)
contemplation/preparation	36	-2.7	(-3.6 to -1.7)	-3.0	(-4.6 to -1.4)	-2.1	(-4.0 to -0.2)
action/maintenance	64	-2.8	(-3.5 to -2.0)	-2.3	(-3.4 to -1.1)	-1.4	(-2.8 to -0.0)
Indication of losing weight[d]							
yes	138	-2.4	(-2.9 to -1.9)	-2.6	(-3.4 to -1.8)	-1.7	(-2.6 to -0.7)
no	8	-2.8	(-4.8 to -0.7)	-0.6	(-3.9 to 2.6)	0.2	(-3.9 to 4.2)
Treatment intention on losing weight							
yes	106	-2.6	(-3.2 to -2.1)	-2.7	(-3.6 to -1.8)	-1.5	(-2.5 to -0.4)
no	24	-1.8	(-3.0 to -0.6)	-2.2	(-4.1 to -0.3)	-2.6	(-4.9 to -0.3)

[a] Adjusted for age, weight change between screening and baseline, BMI at baseline and gender (for 1 man screening data were missing)
[b] $P<.05$
[c] For participants with not normally estimated body weight
[d] Treatment on overweight/obesity indicated according to (inter)national guidelines (motivation of patient not taken into account)

at baseline (P=0.000), the percentage weight change between screening and baseline (P=0.000) and borderline significant with the number of attempts to lose weight in the last 5 year (P=0.054).

Correlation between periods of weight change

Pearson's correlation coefficient (r) between initial weight loss (after 3 months) and weight loss after respectively 12 and 36 months were 0.54 and 0.41 (both P<.01). In the same periods, Pearson's correlation coefficients for men are higher than for women, higher for participants who never did an attempt to lose weight than participants with at least one attempt, higher for participants < 60 years than for elder participants and higher for BMI ≥ 30 kg/m^2 than for BMI < 30 kg/m^2. No clear differences were found for educational level. All correlation coefficients are P<.05 with the exception of elder participants and women (after 36 months) (data not shown).

DISCUSSION

The results of our study on weight maintenance provided by NP in primary care showed that a large part (66%; 73% in men) of the participants achieved long term weight maintenance and that participants who never did an attempt to lose weight during the last five years more often achieved weight maintenance than participants with at least one attempt. Weight change was not consistently related to demographic characteristics like gender, age and education. Important pre-treatment factors that predict weight loss were the number of recent attempts to lose weight, BMI at baseline and the percentage of weight loss between screening and baseline and, perhaps surprisingly, not self-efficacy and not motivation to lose weight.

We found that a higher number of recent dieting attempts was related with less weight loss in accordance to other investigations [4-7] but not with higher self-efficacy while this was reported from other studies [6, 8, 9]. In contrast Martin et al found that higher self-efficacy before treatment was associated with less weight loss but improvements in self-efficacy during treatment were related with greater weight loss [23].

Most of the studies aimed at weight loss in healthy patients, the focus of the GOAL-study was to prevent weight gain in a group with hypertension and dyslipedemia, or both besides a BMI between 25 and 40 kg/m^2. This makes it difficult to compare our results to other investigations. The follow-up time also differed and was in most other studies shorter. Different definitions of weight maintenance were used, some even defining weight maintenance as an at least

10% loss of body weight for a minimum of one year, while we aimed at maintenance without a preceding period of substantial weight loss.
Strength of motivation to lose weight was not associated with long term weight loss. This can be caused by a selection bias because trial participants are by definition volunteers, and for the current trial a selection of motivated patients. In daily practice the GP is responsible for the treatment of hypertension and/or dyslipedemia and according to the guidelines this includes lifestyle counselling [24]. Motivation to comply with lifestyle advices will play a greater role so future guidelines should contain more information how to deal with a possible lack of motivation.
Peculiarly, the increase in weight change between screening and baseline visit was an important predictor of subsequent weight loss during the study intervention. Between the screening and the start of the intervention participants on average gained some weight (with a higher increase associated with a larger subsequent weight loss. A limitation is the time period between screening and baseline. The precise date of screenings visits was not registered. Due to the decentralised recruiting process the time between screening and baseline varied from 7 to 13 months. Also seasonal differences might have influenced this weight gain (increase in body weight during winter). It is possible that participants paid less attention to their body weight in the months before the start of the intervention.
Some limitations of this study needs to be discussed. At first, the large percentage of participants (35%) who did not complete all measurements. Although not unusual in lifestyle interventions [25, 26] this might have influenced our results. But analyses with BOCF and the analyses after 12 months where we include 201 participants (in stead of 147) did not substantially alter the results. Non-completers more often had the intention not to lose weight at baseline. The GOAL study population was identified on the presence of hypertension or dyslipidemia, apparently perceived body weight is not yet sufficiently seen as a (cardiovascular) risk factor in a first line setting. Also a large part of the participants (especially in men) estimated their own body weight as normal although their BMI > 25 kg/m^2.
Second, the predicted variance of weight change is low (after 12 months R^2 = 0.215; after 36 months R^2 =0.135) what means that other predictors are missing. The R^2 in the models to predict weight change is comparable to other studies where similar determinants were used [5, 7, 9]. Additional research is needed on other determinants of weight change and on the underlying mechanism which are not obvious.
Strengths are the large study population (with an equal amount of male and female in a realistic general practice setting and the long term follow up. We

also had a heterogeneous population and the possibility to pay attention to demographic characteristics of the participants which have been hardly analysed as predictors of weight loss. In our study demographic characteristics played no important role in weight maintenance.

Identifying predictors of weight loss is necessary to make adaptations to the lifestyle intervention on subgroups with the same characteristics (e.g. BMI above 30 kg/m^2), to increase the percentage of successful participants and to avoid potential unsuccessful persons to participate. In our intervention participants with a large number of recent attempts to lose weight might be better off not to start to prevent them from another disappointment in weight maintenance. Perhaps this subgroup might be better able to maintain their weight by group sessions or by counselling with more attention on psychological aspects.

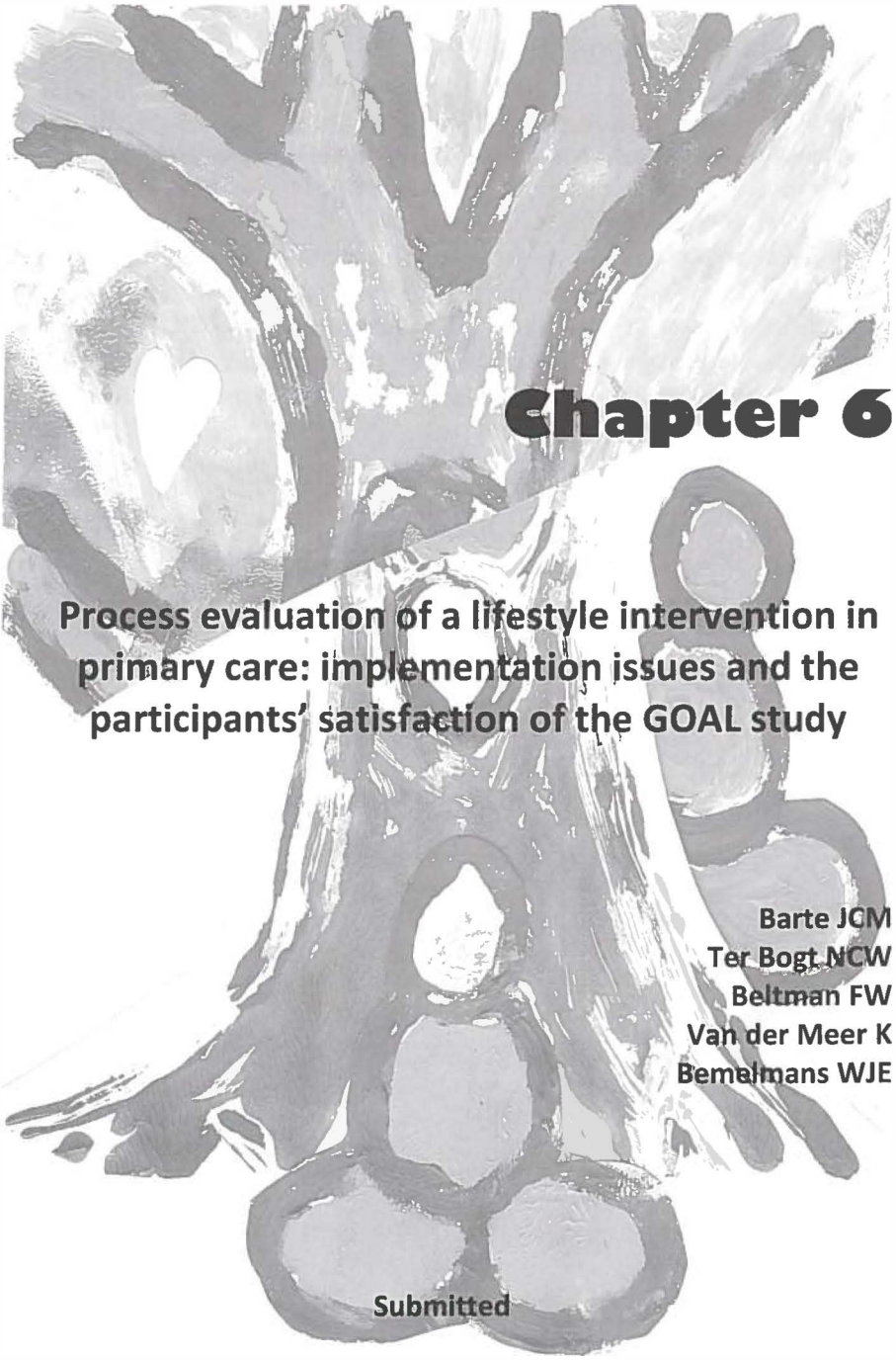
The decline in successful weight maintenance between 12 and 36 months from 81% to 66% might be counteracted by more contact sessions after the first 12 months. Bogers et al found that higher intervention costs (indicative for the intensity of an intervention) are associated with higher weight loss [27], but this applied to weight loss after 1 year. Whether this also holds for the longer term remains to be proven.

In conclusion, long term weight maintenance by NP is possible using a lifestyle intervention in a first line setting. Participants with a higher BMI and with no recent attempt to lose weight were more often successful. Motivation and self-efficacy were no predictors of successful weight change.

REFERENCES

1. Branca F, Nikogosian H, Lobstein T. *The challenge of obesity in the WHO European Region and the strategies for response*. Copenhagen: WHO Regional Office for Europe; 2007.
2. Pi-Sunyer X. A clinical view of the obesity problem. *Science*. 2003; 299(5608):859-860.
3. Serdula MK, Khan LK, Dietz WH. Weight loss counseling revisited. *JAMA*. 2003; 289(14):1747-1750.
4. Kiernan M, King AC, Kraemer HC, Stefanick ML, Killen JD. Characteristics of successful and unsuccessful dieters: an application of signal detection methodology. *Ann Behav Med*. 1998; 20(1):1-6.
5. Teixeira PJ, Going SB, Houtkooper LB, et al. Weight loss readiness in middle-aged women: psychosocial predictors of success for behavioral weight reduction. *J Behav Med*. 2002; 25(6):499-523.
6. Teixeira PJ, Going SB, Houtkooper LB, et al. Pretreatment predictors of attrition and successful weight management in women. *Int J Obes Relat Metab Disord*. 2004; 28(9):1124-1133.
7. Teixeira PJ, Palmeira AL, Branco TL, et al. Who will lose weight? A reexamination of predictors of weight loss in women. *Int J Behav Nutr Phys Act*. 2004; 1(1):12.
8. Dennis KE, Goldberg AP. Weight control self-efficacy types and transitions affect weight-loss outcomes in obese women. *Addict Behav*. 1996; 21(1):103-116.
9. Palmeira AL, Teixeira PJ, Branco TL, et al. Predicting short-term weight loss using four leading health behavior change theories. *Int J Behav Nutr Phys Act*. 2007; 4:14.
10. Teixeira PJ, Going SB, Sardinha LB, Lohman TG. A review of psychosocial pre-treatment predictors of weight control. *Obes Rev*. 2005; 6(1):43-65.
11. Blokstra A, Burns CM, Seidell JC. Perception of weight status and dieting behaviour in Dutch men and women. *Int J Obes Relat Metab Disord*. 1999; 23(1):7-17.
12. French SA, Jeffery RW. Consequences of dieting to lose weight: effects on physical and mental health. *Health Psychol*. 1994; 13(3):195-212.
13. Serdula MK, Mokdad AH, Williamson DF, Galuska DA, Mendlein JM, Heath GW. Prevalence of attempting weight loss and strategies for controlling weight. *JAMA*. 1999; 282(14):1353-1358.
14. Paeratakul S, White MA, Williamson DA, Ryan DH, Bray GA. Sex, race/ethnicity, socioeconomic status, and BMI in relation to self-perception of overweight. *Obes Res*. 2002; 10(5):345-350.
15. Yancey AK, Simon PA, McCarthy WJ, Lightstone AS, Fielding JE. Ethnic and sex variations in overweight self-perception: relationship to sedentariness. *Obesity (Silver Spring)*.2006; 14(6):980-988.
16. NIH. The practical guide: identification, evaluation and treatment of overweight and obesity in adults. 2000;Number 00-4084.
17. Ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, Van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. *Am J Prev Med*. 2009; 37(4):270-277.
18. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd*. 2004; 148(42):2060-2066.

19. Health Council of the Netherlands. *Guidelines for a healthy diet 2006.* The Hague: Health Council of the Netherlands; 2006. Publication no. 2006/21.
20. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. *Am J Health Promot*. 1997; 12(1):38-48.
21. Laforge RG, Velicer WF, Richmond RL, Owen N. Stage distributions for five health behaviors in the United States and Australia. *Prev Med*. Jan 1999;28(1):61-74.
22. Hausenblas HA, Dannecker EA, Downs DS. Examination of the Validity of a Stages of Exercise Change Algorithm. *Journal of Applied Social Psychology*. 2003;33(6):1179-1189.
23. Martin PD, Dutton GR, Brantley PJ. Self-efficacy as a predictor of weight change in African-American women. *Obes Res*. Apr 2004;12(4):646-651.
24. Dutch Institute for Healthcare Improvement (CBO). *Dutch Guideline Cardiovascular Risk Management.* Utrecht 2006.
25. Anderson JW, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. *Am J Clin Nutr*. November 1, 2001 2001;74(5):579-584.
26. Tsai AG, Wadden TA. Treatment of obesity in primary care practice in the United States: a systematic review. *J Gen Intern Med*. Sep 2009;24(9):1073-1079.
27. Bogers R, Barte J, Schipper C, et al. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obesity Reviews*. 2010;11(1):51-61.



Chapter 6

Process evaluation of a lifestyle intervention in primary care: implementation issues and the participants' satisfaction of the GOAL study

Barte JCM
Ter Bogt NCW
Beltman FW
Van der Meer K
Bemelmans WJE

Submitted

ABSTRACT

The Groningen Overweight And Lifestyle (GOAL)-intervention effectively prevents weight gain. The present study describes a process evaluation in which 214 participants in the intervention group received a structured questionnaire within seven months after the end of the intervention. We investigated the actual content, the participants' satisfaction of the intervention, the participants' satisfaction of the nurse practitioners (NP) and the determinants of the participants' satisfaction. In general, the results show that the actual content corresponded well with the protocol for the intervention, except for the number of telephone calls and the percentage of participants with individualized goals for a healthy lifestyle. The overall satisfaction of the participants was high and success and perceived success and a low educational level were important determinants for a higher overall satisfaction grade. Furthermore, the NP was considered to be an expert and motivational to learning and keeping up a healthy lifestyle. We therefore conclude that the GOAL study is feasible and indicates that the NP is well equipped to treat these patients.

INTRODUCTION

Obesity is a problem on a global scale with serious consequences in terms of public health. The World Health Organization has indicated that worldwide approximately 1.6 billion adults were overweight or obese in 2005 and they predicted that this would rise to 2.3 billion in 2015 [1]. Overweight and obesity are associated with health issues such as diabetes, high blood pressure, high cholesterol concentrations, asthma, different types of cancers, coronary heart disease and a diminished quality of life [2-6]. Because of these serious health consequences, counteracting the ongoing obesity epidemic remains a high priority.

On an individual level, lifestyle changes are needed to improve the health of overweight and obese patients and the Groningen Overweight And Lifestyle (GOAL) intervention has assisted its participants in this aim. Lifestyle interventions, such as the GOAL-intervention, are interventions guided by health professionals aiming at changes in the dietary and physical activity behaviour of participants. Lifestyle interventions have already shown that lifestyle changes are effective in reducing weight [7, 8], but lifestyle changes without weight loss can also result in improved health (e.g. increased insulin sensitivity, improved blood glucose control and a decrease in total and visceral fat [9-11]). Moreover, lifestyle interventions can be considered as relatively inexpensive compared to pharmacological interventions and surgery [12].

In the Netherlands, participants with hypertension and/or dyslipidemia are usually treated by general practitioners (GPs), but these doctors report a lack of time and knowledge to achieve behavioural changes [13]. The GOAL-intervention is designed to investigate long-term effects of lifestyle counselling by specially trained nurse practitioners (NPs) compared to usual care by GPs. It has already been shown that the GOAL intervention positively changes physical activity and nutrition intake [14]. Furthermore, weight gain was prevented in the intervention group. After one year of follow-up, a mean weight loss of 1.9% was found [15] and after three years follow-up, the mean weight loss was 1.2% [16].

Besides an evaluation of the effects of an intervention program, its process also needs to be evaluated [17-19]. A process evaluation describes specific program components, can assess the quality of an intervention program, and is used to investigate whether a program has been carried out as planned [20]. Evaluating the implementation of the intervention can avoid incorrect conclusions about its effectiveness due to inadequate implementation [20]. Furthermore, a process evaluation examines the participants' view of the intervention [17]. The satisfaction of participants is an important health outcome, predicts attrition, and is used to evaluate quality of care and to determine aspects to improve [21, 22].

However, the determinants of participants' satisfaction remain largely unknown [21, 22]. Previous research has shown that age and baseline health status may influence satisfaction, while sex and race do not seem to [21]. Also, health related outcomes are important to patient satisfaction [23]. A recent evaluation of a behavioural weight-loss program showed that success (BMI loss, physical activity increase and improved diet quality) and perceived success (improved body image) were predictors of overall program satisfaction [22]. It also showed that educational level was related to whether or not participants would refer the program to others.

Thus, a process evaluation can evaluate and improve the quality of an intervention, which is useful in case of further implementation of the investigated and other lifestyle interventions. The present study aims to evaluate the content and the participants' satisfaction of the GOAL-intervention. We focus on the actual content of the intervention as compared to the protocol, the participants' satisfaction with the intervention components, the participants' satisfaction with the NP and the overall satisfaction of the GOAL-intervention. We also investigate what factors of success and perceived success and which characteristics of the participants determine the overall satisfaction of the participants.

METHODS

GOAL study description

For the GOAL study, overweight and obese individuals (a body mass index (BMI) of 25-30 and ≥30 kg m^{-2}) from the northern part of the Netherlands were screened for eligibility. From 11 general practice locations, 457 participants (aged 40-70) with a BMI between 25-40 kg/m^2 with hypertension and/or dyslipidemia were randomized into an intervention group (N=225) and a control group (N=232).

The participants in the intervention group had lifestyle counselling by NPs. The intervention is shown in Table 1 (see introduction in this thesis) and contained four individual visits and one telephone call in the first year. In the second and third years of the intervention, participants visited the NP once a year and telephone calls were made twice a year. During the contact sessions, the NPs were guided by a standardized software program, for which they were specially trained.

In the first two visits participants received information and individual advice on healthy lifestyle (healthy eating and physical activity), were given feedback on their lifestyle by discussing their food diary, their pedometer results and their baseline questionnaires and developed a treatment plan with individual goals. Standard advice for healthy living was based on national and international

guidelines [24, 25]. According to the protocol, every participant had to set a goal to lose weight, to prevent weight gain or to achieve a healthy lifestyle without a focus on weight. In addition, for every participant, individual goals on healthy eating and physical activity were set. Participants with a weight loss goal were advised to reduce caloric intake by 300-500 kcal/day.
In the contact sessions thereafter, the NP evaluated lifestyle and lifestyle changes, discussed potential barriers and experiences and adjusted the goals if necessary. Participants in the control group visited the general practitioner once to discuss the screening results, and thereafter they received usual care according to the guidelines [26]. Weight measurements for both groups were at baseline, after one year follow-up and after three years follow-up. More details about the GOAL study can be found elsewhere [15, 16].

Process evaluation
All participants who completed the study were invited for this process evaluation. The dropouts were also included in the evaluation, except for 12 dropouts who moved to another area, were unreachable, had a serious disease or died. A request to complete a questionnaire with multiple-choice questions was sent to 213 participants of the intervention group within seven months after the end of the intervention. The main topics of this questionnaire were the actual content of the intervention and the participants' satisfaction with it. These items from the questionnaire are shown in Tables 2-4. Furthermore, the questionnaire contained questions about the perceived success of participants (whether they felt healthier, felt fitter and had fewer health complaints than before the GOAL study and whether they were satisfied with the results on weight control). If participants did not respond to this questionnaire, we sent the questionnaire again together with a shortened version, which could be returned if the participant was not willing (or not able to) complete the original questionnaire. This shortened questionnaire contained questions about the reason for not responding to the original questionnaire and about the overall score of the intervention.
All participants of the intervention group who returned the original questionnaire were included in the analyses, except for participants who had not had any contact sessions with the NP and participants who did not answer the large majority of the questions. The participants who returned the shortened questionnaire were only included in the analyses of the overall score of the intervention.

Statistical analyses

Differences in baseline characteristics (gender, educational level, baseline BMI, age and history of dieting), percentage of weight loss after three years and number of dropouts between the participants who responded and did not respond on the original questionnaire were investigated using an independent sample t-test and a chi-square test.

The actual content and the participants' satisfaction with the GOAL-intervention were described by frequencies of the answer categories. Also, the mean grade of the intervention was calculated. All aspects of the participants' satisfaction of the intervention were also compared for the following subgroups: successful participants (<1% weight gain) versus non-successful participants (≥1% weight gain), men versus women, a BMI between 25 and 30 kg/m^2 versus a BMI of at least 30 kg/m^2 and a high or intermediate educational level versus low educational level. Differences between these subgroups were tested using independent t-tests and chi-square tests.

To examine which factors determine the participants' satisfaction, the association of the overall grade of the participants' satisfaction with success and perceived success and the characteristics of participants were investigated using independent sample t-tests, Pearson correlations and a linear trend analyses. Success or perceived success contained the following items: feeling healthier than before the GOAL study, feeling fitter than before the GOAL study, having fewer health complaints than before the GOAL study, satisfaction with the results on weight control and weight loss after three years. The characteristics of participants which were investigated as determinants of the participants' satisfaction were: gender, a low educational level, baseline BMI, age and history of dieting.

SPSS 18.0 was used to perform the analyses and a significance level of .05 was considered significant.

RESULTS

Response to questionnaire

150 (70%) of the original questionnaires were returned. Of the 64 non-responders, 13 (20%) returned the shortened version and the reported reasons for not responding were 'it takes too much time' (n=4), 'it was too long ago, I cannot remember the intervention very well anymore' (n=4) and other reasons (n=5). After excluding two participants because they had had no contact sessions with the NP and two others who had not answered most of the questions, we included 146 participants in our analyses and 159 participants in the analyses for the overall appreciation of the study. Baseline characteristics

(gender, educational level, baseline BMI, age and history of dieting) and weight loss after three years did not significantly differ between responders and non-responders. However, intervention dropouts (n=38) responded less to the questionnaire ($P<0.001$).

Table 2 The actual content of the intervention

	Answer categories	Percentage Participants (n=146)
Number of visits to the NP	<5	19
	5-10	63
	>10	19
Number telephone calls with the NP	0	63
	1	7
	2	14
	3 or more	17
Number of different NPs who guided the participant	1	55
	2	27
	3 or more	18
The participant received individual goals for healthy eating	Yes	67
	No	30
	Can't remember	3
The participant received individual goals for physical activity	Yes	60
	No	38
	Can't remember	1
The participant received individual goals for weight control	Yes	85
	No	14
	Can't remember	1
The participant received advice on healthy eating	Yes	81
	No	19
The participant received advice on physical activity	Yes	59
	No	41

Participants' satisfaction of the GOAL-intervention

Table 3 describes the participants' satisfaction regarding the different components of the intervention. Most participants perceived the total number of contact sessions as good (63%) and most of the participants who received phone calls were satisfied with these calls (76%). More than 80% of the participants were positive or neutral about the usefulness of the food diary and the pedometer, and 76% of the participants agreed with the usefulness of the individual lifestyle goals.

Table 3 The percentage of participants who were satisfied with the intervention (components)

	Answer categories	Total (n=146) [a]	Low educat. level (n=46) [a]	Successful (<1% weight gain) (n=86) [a]	BMI < 30 kg/m^2 (n=97) [a]	Males (n=70) [a]
Number of contact sessions	The number was exactly right	63	60	66	64	69
	I preferred less contact sessions	3	4	2	3	4
	I would have preferred more	11	4	7	10	9
	No opinion	23	31	24	23	18
Satisfied with telephone calls	(Totally) agree	76	91 [b]	80	79	79
	Neutral	17	9	15	13	13
	(Totally) disagree	8	0	5	8	8
Useful food diary	(Totally) agree	62	63	64	59	64
	Neutral	19	24	20	22	16
	(Totally) disagree	9	4	7	7	9
	Not applicable	9	9	9	12	11
Useful pedometer	(Totally) agree	74	76	75	79	77
	Neutral	14	15	14	11	13
	(Totally) disagree	11	7	11	9	10
	Not applicable	1	2	0	0	0
Useful individual lifestyle goals	(Totally) agree	76	76	76	68	80
	Neutral	18	20	16	22	16
	(Totally) disagree	0	0	0	0	0
	Not applicable	5	4	8	10	4
NP was an expert	(Totally) agree	87	91	91	90	90
	Neutral	10	9	8	8	7
	(Totally) disagree	2	0	1	2	3
NP was motivational	(Totally) agree	82	96	89 [c]	84	86
	Neutral	16	4	11	16	15
	(Totally) disagree	2	0	0	1	0
Possible to discuss everything with NP	(Totally) agree	85	100 [b]	87	84 [d]	87
	Neutral	13	0	11	14	10
	(Totally) disagree	1	0	2	2	3

Continues on next page

Other personal matters (besides lifestyle) were also discussed with NP	(Totally) agree	43	52 [b]	43	35 [d]	38
	Neutral	31	37	38	33	32
	(Totally) disagree	25	11	19	32	30
Satisfied with the visits to the NP	(Totally) agree	91	100 [b]	94	91	90
	Neutral	8	0	5	8	9
	(Totally) disagree	1	0	1	1	1
Lifestyle advice is a useful addition to existing health care	(Totally) agree	79	83	85	77	86
	Neutral	20	17	16	21	13
	(Totally) disagree	2	0	0	2	1
Prolongation contact sessions wanted	Yes	24	24	19	21	30
	No	43	39	46	50	45
	Maybe, do not know yet	30	33	33	27	22
	No opinion	2	4	1	2	3
Afterwards happy with participation	Yes, I would certainly do it again	61	64	66	60	67
	Yes, somewhat	30	34	28	32	29
	No, not really	5	2	5	4	3
	No, afterwards I would prefer not to participate	4	0	1	4	1
Overall appreciation of the intervention	<4	0	0 [b]	0 [c]	0	0
	4	3	0	0	2	3
	5	3	4	2	2	3
	6	10	4	6	10	7
	7	34	29	28	41	38
	8	36	44	47	35	37
	9	9	10	10	7	11
	10	5	8	7	4	3

[a] The number of participants for the overall appreciation of the intervention was 159. For the subgroups low educational level, successful, BMI<30 kg/m^2 and males the number of participants for the overall appreciation was 48, 87, 103 and 76, respectively.

[b] $p<0.05$ for the difference between participants with a low educational level and participants with an intermediate or high educational level.

[c] $p<0.05$ for the difference between successful and unsuccessful participants.

[d] $p<0.05$ for the difference between participants with a baseline BMI of <30 kg/m^2 and ≥ 30 kg/m^2.

The participants' satisfaction on the advice given by the NP is shown in Table 4. More than 80% of the participants who received advice found the advice on healthy eating and physical activity useful. The advice on healthy eating fitted in the daily practice of 77% of the participants, while this was only 61% for the advice on physical activity. About 60% of the participants agreed that the advice on healthy eating and physical activity added knowledge to their existing knowledge on these topics.

Table 4 The participants' satisfaction with the advice given on healthy eating and physical activity

	Answer categories	Healthy eating advice (% participants) (n=117)	Physical activity advice (% participants) (n=86)
Useful advice	Totally agree	19	14
	Agree	65	67
	Neutral	15	16
	Disagree	1	1
	Totally disagree	0	1
Advice fitted in daily practice	Totally agree	13	7
	Agree	64	54
	Neutral	20	27
	Disagree	3	11
	Totally disagree	0	1
Advice added knowledge	Totally agree	17	8
	Agree	44	47
	Neutral	29	31
	Disagree	10	13
	Totally disagree	1	1

The participants were satisfied with the NP (as shown in Table 3). Most participants were satisfied with the visits to the NP (91%), agreed that the NP was an expert (87 %), and agreed that the NP was motivational regarding learning and keeping up a healthy lifestyle (82%). Moreover, some participants agreed (43%) and some disagreed (25%) that they had discussed other personal matters (besides lifestyle) with the NP. However, most participants agreed that it was possible to discuss everything they wanted with the NP.
Furthermore, Table 3 shows the overall satisfaction with the GOAL-intervention. Most participants agreed that the lifestyle advice (as in the GOAL

study) is a useful addition to the existing health care service and prolongation of the intervention was preferred by 24% of the participants, while 43% did not want prolongation and 30% was unsure. Overall, the participants were happy with the intervention and 61% would certainly participate again. The average score of the intervention was 7.5 (SD 1.2) out of a possible 10. It appeared that the 146 respondents of the original questionnaire scored the intervention higher than the respondents of the shortened questionnaire (7.5 versus 6.4, respectively; p<0.01).

Subgroup analyses for aspects of participants' satisfaction

Table 3 shows the results of the subgroups for low educational level, successful participants, overweight participants and males. The subgroup analyses of the aspects of the participants' satisfaction showed that successful participants agreed more often than unsuccessful participants that the NP was motivational (89% vs. 76%, *P*=0.02) and that advice on healthy lifestyle added knowledge (71% vs. 44%, *P*<0.01 for healthy eating; 69% vs. 38%, *P*=0.02 for physical activity). Of the males, 71% agreed that the advice on healthy eating added knowledge to their existing knowledge compared to 51% of the females (*P*=0.02). Participants with a BMI of at least 30 kg/m^2 agreed more often that it was possible to discuss everything with the NP (89%) than participants with a BMI below 30 kg/m^2 (84%, *P*=0.04), and they also discussed personal matters more often (62% vs. 35%, *P*<0.001). Participants with a low educational level agreed more that they were satisfied with the telephone calls (91% vs. 68%, p=0.04), that it was possible to discuss everything with the NP (100% vs. 79%, *P*=0.02), that they discussed personal matters with the NP (52% vs. 40%, *P*=0.02), that they were satisfied with the visits to the NP (100% vs. 87%, *P*=0.04) and that advice on physical activity added knowledge to their existing knowledge on that topic (79% vs. 44%, *P*<0.001). Also, it seemed that participants with a low educational level agreed more that advice on healthy eating added knowledge (69% vs. 56%, *P*=0.08) and that advice on physical activity fitted into their daily practice (69% vs. 57%, *P*=0.05).

Associations with participants' overall satisfaction

We also investigated whether success and perceived success and the characteristics of participants could explain the participants' overall satisfaction grade of the intervention. Feeling healthier after the GOAL study (*P*<0.001), feeling fitter after the GOAL study (*P*<0.001) and perceiving fewer health complaints after the GOAL study (*P*<0.001) were significantly associated with a higher overall score of the intervention. Also, the percentage of weight loss after three years (*P*<0.001) and being satisfied with results on weight control

(P<0.001) correlated positively with the overall score. Concerning the characteristics of the participants, only educational level showed a significant association, i.e. a low educational level was associated with a higher overall score of the intervention (P=0.04).

DISCUSSION

The present study evaluates the process of the GOAL-intervention and focuses on the content of the intervention and the satisfaction of participants. In general, the actual content (i.e. the number of visits to the NP, individual goals for weight control and advice on healthy eating) was similar to the protocol of the intervention, and the participants were satisfied with the intervention (components). More than 90% were happy with their participation and the overall satisfaction grade was 7.5 out of a possible 10, which is comparable both to satisfaction grades of health care and to a recent Dutch lifestyle intervention [27, 28].

Nevertheless, some elements of the intervention were not well implemented for all participants and should be improved in further implementation. First, 62.8% of the participants did not receive any telephone calls during the intervention, while the protocol prescribes 5 telephone calls. Previous studies indicated that transportation is a perceived barrier to self-management [29] and a reason for non adherence [30] and that telephone calls may be useful in an intervention as an alternative to expensive face-to-face visits [31]. However, a few NPs indicated to the investigators that they substituted telephone contacts for face-to-face contacts, because they preferred face-to-face contact due to practical issues involved with the telephone calls, e.g. not easily being able to contact the participants and a higher adherence to face-to-face visits. This means that the implementation of the intervention did not fully comply with the protocol, which could lead to incorrect conclusions about the effectiveness of the intervention. However, these alterations in the program were only conducted by a few NPs and therefore the protocol was followed in a large extent. Second, the percentages for participants with individual goals on healthy eating (67%) and physical activity (60%) were surprisingly low. This may partly be explained by participants who already met the guidelines on baseline and therefore did not receive an individual goal on this topic. However, for healthy eating it is less likely that participants already met all criteria on baseline [14]. Therefore, the number of individual goals on a healthy lifestyle should be improved in further implementation, since goals on behaviour change have a positive effect on dietary and physical activity behaviours [32]. Finally, some of the participants reported that they did not receive any advice

on healthy eating and physical activity (19% and 41%, respectively). However, the instructions for the NP in the protocol and the standardized software program were strict regarding advice on a healthy lifestyle. Therefore, it is more likely that the participants did not remember the advice anymore or did not recognize it as advice for a healthy lifestyle. This may be due to the time (more than 3 years) between the beginning of the intervention and the moment the questionnaire was sent.

Participants were on average satisfied with all intervention components, and the advice on a healthy lifestyle was considered useful and fitted in reasonably well with the daily lives of the participants. Participants who felt healthier, who felt fitter and who had fewer health complaints than before the GOAL study were more satisfied with the GOAL-intervention. Weight loss after three years was also associated with the overall grade, which implies that success and perceived success of the intervention were important determinants for the participants' satisfaction of the intervention.

Participants with a low educational level also regarded the advice as useful and they indicated that the advice on healthy lifestyle added more knowledge compared with the participants with a higher educational level. Advice on physical activity also fitted better into the daily lives of participants with a low educational level. This can be explained by the study of Ball et al. [33] who found that women with a low socio-economic status participate more in transport-related activity and are more likely to be active at work. However, they also found that people from a low socio-economic status tend to have a lack of time due to work commitments and a lack of flexibility of working hours. Furthermore, advice on healthy eating added more often knowledge to men to women. This may be due to the higher number of weight loss attempts for women compared to men [34], which can lead to more knowledge on healthy eating for women at the start of this intervention.

A great strength of the present study is that we systematically investigated the actual content and the participants' satisfaction of participants in the intervention group using standardized questionnaires, whereas often data are not systematically collected for a process evaluation [17]. However, a few limitations of this evaluation should also be mentioned. First, the analyses on the content and the participants' satisfaction of the intervention are based on self-reported data and therefore data on the actual content of the intervention may be less accurate than measured data would have been. Second, the intervention was not totally implemented as designed, because not all participants were contacted by telephone. The reasons for missing the phone calls were not measured in this evaluation; possible reasons could be due to the NP as well as the participant. However, a few NPs indicated to the

investigators that it was not always easily to contact the participants and participants had a higher adherence to face-to-face visits than to the phone-call appointments. Third, only univariate analyses were used to investigate the determinants of the participants' satisfaction, because the multivariate outcomes were susceptible to changes in the equation. However, results were similar for the multivariate analyses. Finally, participants who dropped out of the intervention responded less to the questionnaire and participants who responded to the shortened questionnaire scored the intervention lower. Despite the high response in our study, this could bias our results resulting in a small overestimation of the quality of the intervention and the participants' satisfaction.

To summarize, the obesity epidemic is a problem with serious health consequences. The GOAL study investigates the long-term effects of lifestyle intervention by NPs and it has been shown that it effectively prevents weight gain in contrast to the Dutch population in which BMI increases on average 0.05 kg/m^2 per year [35]. This study evaluated the process of the intervention and showed that the actual content corresponded with the protocol to a large extent and that the participants' satisfaction was high, which makes this intervention feasible. Furthermore, the GOAL-intervention has a relative low intensity and the majority of the participants thought no more contact sessions were needed, which makes the intervention relatively inexpensive.

IMPLICATIONS FOR PRACTITIONERS

This evaluation shows some elements (e.g. telephone calls, healthy lifestyle goals and advice on a healthy lifestyle) which should be improved in further implementation of the GOAL study and which should be kept in mind for the implementation of other interventions. For further implementation, the protocol with regard to telephone calls should be changed. An appointment for this contact session should be made in advance (preferably during the face-to-face session). Also, there should be an opportunity for NPs and participants to replace the phone calls when participants are difficult to contact by phone or are unwilling to be contacted for sessions by phone. For example, the phone calls could be replaced by email or face-to-face contacts. Furthermore, some participants could not remember the advice given anymore. Therefore, additional reinforcement after the first contact sessions is needed for these recommendations. This may be realized by the deliverance of written information or guidelines and by oral reinforcement by the NP.

This study shows that higher educated participants were less satisfied with the GOAL study, which can be explained by the fact that the advice on a healthy lifestyle did not add to their existing knowledge and that advice on physical activity did not fit well into their daily lives. The degree to which advice on healthy eating added knowledge also differed by gender. These differences should be borne in mind by NPs (and other health professionals) when adjusting advice on a healthy lifestyle to the characteristics of the participant. For some participants advice on a healthy lifestyle may not even be the priority, and the main task of the NP will be to motivate the participants involved.

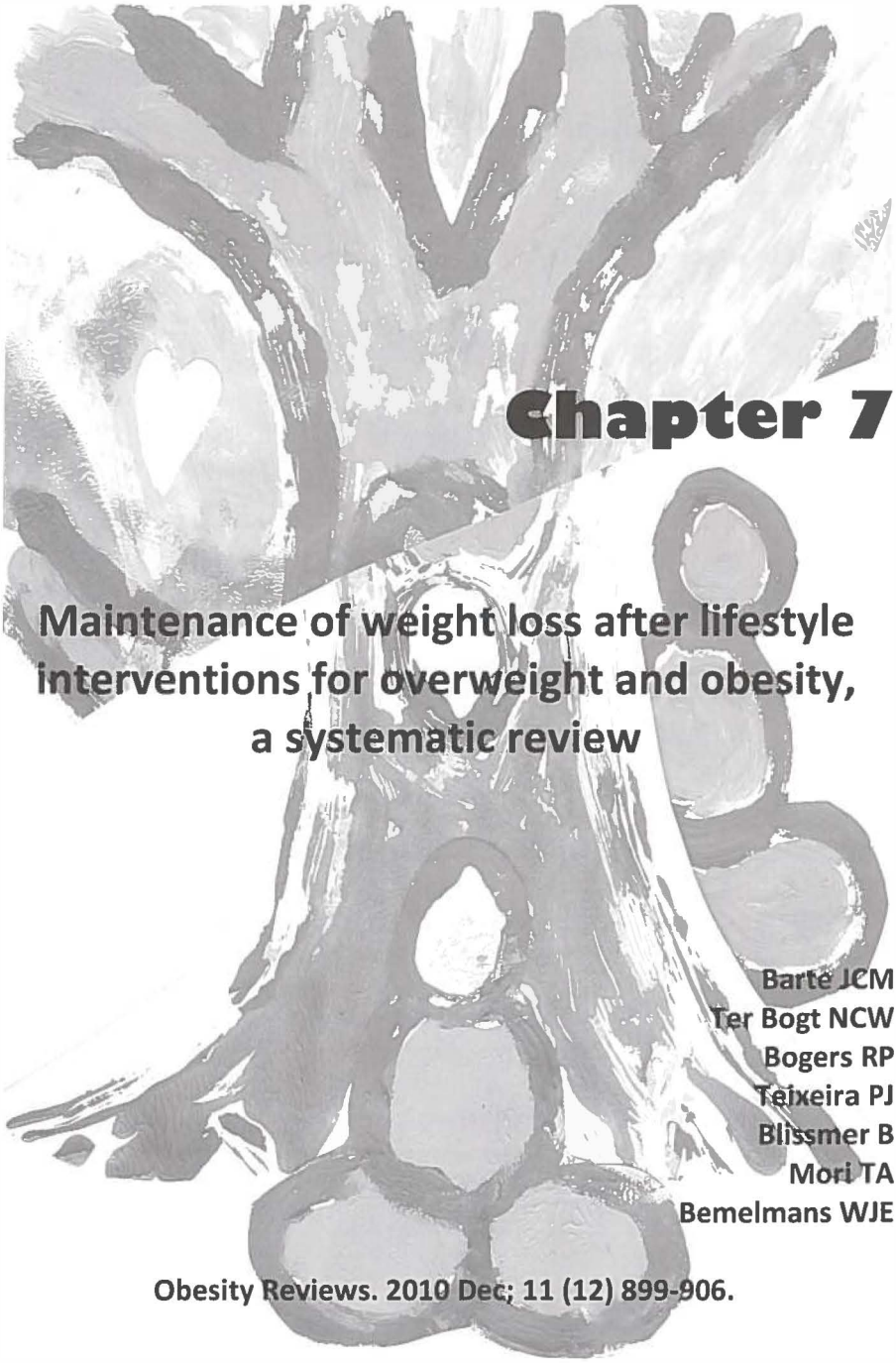
The GOAL study evaluates a lifestyle intervention conducted by NPs. Previous research [15, 16] showed that this intervention was effective in preventing weight gain and the present study shows that the participants were satisfied with the NP. In general, the NP was considered both expert and motivational regarding the participants learning and keeping up a healthy lifestyle. Therefore, the GOAL study indicates that the NP is well equipped to treat these patients.

REFERENCES

1. WHO. *Factsheet n 311. Obesity and overweight*. Geneva 2006.
2. Bogers RP, Bemelmans WJ, Hoogenveen RT, et al. Association of overweight with increased risk of coronary heart disease partly independent of blood pressure and cholesterol levels: a meta-analysis of 21 cohort studies including more than 300 000 persons. *Arch Intern Med*. 10 2007; 167(16):1720-1728.
3. Carroll K. Obesity as a risk factor for certain types of cancer. *Lipids*. 1998; 33(11):1055-1059.
4. Field AE, Coakley EH, Must A, et al. Impact of overweight on the risk of developing common chronic diseases during a 10-year period. *Arch Intern Med*. Jul 9 2001; 161(13):1581-1586.
5. Fontaine KR, Barofsky I. Obesity and health-related quality of life. *Obes Rev*. 2001; 2(3):173-182.
6. Mokdad AH, Ford ES, Bowman BA, et al. Prevalence of obesity, diabetes, and obesity-related health risk factors, 2001. *JAMA*. 2003; 289(1):76-79.
7. Curioni CC, Lourenco PM. Long-term weight loss after diet and exercise: a systematic review. *Int J Obes (Lond)*. 2005; 29(10):1168-1174.
8. Douketis JD, Macie C, Thabane L, Williamson DF. Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *Int J Obes (Lond)*. 2005; 29(10):1153-1167.
9. Duncan GE, Perri MG, Theriaque DW, Hutson AD, Eckel RH, Stacpoole PW. Exercise training, without weight loss, increases insulin sensitivity and postheparin plasma lipase activity in previously sedentary adults. *Diabetes Care*. 2003; 26(3):557-562.
10. Gannon MC, Nuttall FQ. Control of blood glucose in type 2 diabetes without weight loss by modification of diet composition. *Nutr Metab (Lond)*. 2006; 3:16.
11. Lee S, Kuk JL, Davidson LE, et al. Exercise without weight loss is an effective strategy for obesity reduction in obese individuals with and without Type 2 diabetes. *J Appl Physiol*. 2005; 99(3):1220-1225.
12. Bogers R, Barte J, Schipper C, et al. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obesity Reviews*. 2010; 11(1):51-61.
13. Hiddink GJ, Hautvast JG, Van Woerkum CM, Fieren CJ, van 't Hof MA. Driving forces for and barriers to nutrition guidance practices of Dutch primary care physicians. *Journal of Nutrition Education*. 1997;29:36-41.
14. Ter Bogt NC, Milder IE, Bemelmans WJ, et al. Changes in lifestyle habits after counselling by nurse practitioners: 1-year results of the Groningen Overweight and Lifestyle study. *Public Health Nutr*. Jan 28:1-6.
15. Ter Bogt NC, Bemelmans WJ, Beltman FW, Broer J, Smit AJ, Van der Meer K. Preventing weight gain: one-year results of a randomized lifestyle intervention. *Am J Prev Med*. 2009; 37(4):270-277.
16. Ter Bogt NCW, Bemelmans WJE, Beltman FW, Broer J, Smit AJ, Van der Meer K. Preventing weight gain by lifestyle intervention in a general practice setting. Three-year results of a randomised controlled trial. *Arch Intern Med*. 2010; Accepted.
17. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ*. 2006; 332(7538):413-416.

18. Parry-Langdon N, Bloor M, Audrey S, Holliday J. Process evaluation of health promotion interventions. *Policy Polit.* 2003; 31(2):207-216.
19. Rosecrans AM, Gittelsohn J, Ho LS, Harris SB, Naqshbandi M, Sharma S. Process evaluation of a multi-institutional community-based program for diabetes prevention among First Nations. *Health Educ Res.* 2008; 23(2):272-286.
20. Linnan L, Steckler AB, eds. *Process evaluation for public health interventions and research: an overview.* Evaluation for Public Health Interventions and Research. San Fransico: Jossey-Bass; 2002.
21. Jackson JL, Chamberlin J, Kroenke K. Predictors of patient satisfaction. *Soc Sci Med.* 2001; 52(4):609-620.
22. VanWormer JJ, Martinez AM, Cosentino D, Pronk NP. Satisfaction with a weight loss program: what matters? *Am J Health Promot.* 2010; 24(4):238-245.
23. Jatulis DE, Bundek NI, Legorreta AP. Identifying predictors of satisfaction with access to medical care and quality of care. *Am J Med Qual.* 1997; 12(1):11-18.
24. NHLBI Obesity Initiative. *Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults: the evidence report.* Bethesda, MD: NIH; 1998. 98-4083.
25. Zelissen PM, Mathus-Vliegen EM. [Treatment of overweight and obesity in adults: proposal for a guideline]. *Ned Tijdschr Geneeskd.* 2004; 148(42):2060-2066.
26. Dutch Institute for Healthcare Improvement (CBO). *Dutch Guideline Cardiovascular Risk Management.* Utrecht 2006.
27. Hall JA, Dornan MC. Meta-analysis of satisfaction with medical care: description of research domain and analysis of overall satisfaction levels. *Soc Sci Med.* 1988; 27(6):637-644.
28. Harting J, van Assema P, de Vries NK. Patients' opinions on health counseling in the Hartslag Limburg cardiovascular prevention project: perceived quality, satisfaction, and normative concerns. *Patient Educ Couns.* 2006; 61(1):142-151.
29. Jerant AF, von Friederichs-Fitzwater MM, Moore M. Patients' perceived barriers to active self-management of chronic conditions. *Patient Educ Couns.* 2005; 57(3):300-307.
30. Jorgensen WA, Polivka BJ, Lennie TA. Perceived adherence to prescribed or recommended standards of care among adults with diabetes. *Diabetes Educ.* 2002;28(6):989-998.
31. Sherwood NE, Jeffery RW, Pronk NP, et al. Mail and phone interventions for weight loss in a managed-care setting: weigh-to-be 2-year outcomes. *Int J Obes (Lond).* 2006; 30(10):1565-1573.
32. Shilts MK, Horowitz M, Townsend MS. Goal setting as a strategy for dietary and physical activity behavior change: a review of the literature. *Am J Health Promot.* 2004; 19(2):81-93.
33. Ball K, Salmon J, Giles-Corti B, Crawford D. How can socio-economic differences in physical activity among women be explained? A qualitative study. *Women Health.* 2006; 43(1):93-113.
34. Kruger J, Galuska DA, Serdula MK, Jones DA. Attempting to lose weight: specific practices among U.S. adults. *Am J Prev Med.* 2004; 26(5):402-406.
35. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities

in The Netherlands since 1980: stratification according to sex, age and urbanisation degree. *Int J Obes*. 2006; 31(3):515-520.



Chapter 7

Maintenance of weight loss after lifestyle interventions for overweight and obesity, a systematic review

Barte JCM
Ter Bogt NCW
Bogers RP
Teixeira PJ
Blissmer B
Mori TA
Bemelmans WJE

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ABSTRACT

Lifestyle interventions can reduce body weight, but weight regain is common and may particularly occur with higher initial weight loss. If so, one may argue whether the 10% weight loss in clinical guidelines is preferable above a lower weight loss. This systematic review explores the relation between weight loss during an intervention and weight maintenance after at least 1 year of unsupervised follow-up.

Twenty-two interventions (during at least 1 month) in healthy overweight Caucasians were selected and the mean percentage of weight loss and maintenance were calculated in a standardised way. In addition, within four intervention groups (n>80) maintenance was calculated stratified by initial weight loss (0-5%, 5-10%, >10%).

Overall, mean percentage maintenance was 54%. Weight loss during the intervention was not significantly associated with percentage maintenance (r=-0.26; *P*=0.13). Percentage maintenance also not differed significantly between interventions with a weight loss of 5-10% versus >10%. Consequently, net weight loss after follow-up differed between these categories (3.7 vs. 7.0%, respectively; *P*<0.01). The analyses within the four interventions confirmed these findings.

In conclusion, percentage maintenance does not clearly depend on initial weight loss. From this perspective, 10% or more weight loss can indeed be encouraged and favoured above lower weight loss goals.

INTRODUCTION

A recent review of Wu et al. (2009) [1] showed that (lifestyle) interventions with a dietary component result in weight loss, but interventions with both a dietary and a physical activity component result in more weight loss. Other reviews also showed that lifestyle interventions are effective [2-4] and that weight can be reduced at reasonable costs [5]. Despite the short-term effectiveness of lifestyle interventions, long-term weight loss seems to be more difficult [1]. After an intervention weight regain may occur and therefore the weight loss achieved during the intervention may not be fully maintained.

Insight into the relationship between weight loss during an intervention and subsequent maintenance of this weight loss could provide valuable information to set weight loss targets focused on optimal long-term weight loss. Current guidelines prescribe a weight loss of 5-10% for overweight or obese persons [6, 7], because a weight loss of 5% has a beneficial effect on cardiovascular risk factors associated with obesity [8-10] and reduces the risk for diabetes [11]. However, this guideline does not take into account possible weight regain after an intervention. Weiss et al. [12] showed in a survey that a higher percentage weight loss was significantly associated with a higher percentage weight regain. Participants who lost more than 20% of their weight had 2.8 times the risk of weight regain compared with participants who lost 10-15% of their weight. Therefore, it could be hypothesized that people who lose more weight during an intervention will on average maintain less of this weight reduction. In that case, one may argue about the 10% weight loss goal (as compared to 5%) as weight cycling may have adverse health effects.

Previous reviews focused on the effect of exercise on maintenance [2, 13, 14] or long-term weight loss [4, 15, 16]. However, these reviews have not focused on the relationship between short-term weight loss (the amount of weight loss during an intervention) and the maintenance of this weight loss during an unsupervised follow-up. Therefore, the aim of this systematic review was to investigate the relationship between weight loss during a lifestyle intervention (with a dietary and physical activity component) and the maintenance of this weight loss after an unsupervised follow-up period of at least 1 year.

METHODS

Search

The literature search for this study is described previously [5]. Briefly, two search strategies were used to select relevant articles: 1) recent reviews about interventions aiming at weight loss and 2) the MEDLINE database. For the present study, the search was extended to February 2009; the results of the search are shown in Figure 1.

Eligible studies for this review had to meet the following inclusion criteria: overweight or obese adults (mean BMI <40 kg/m^2); mainly Caucasian population; at least one intervention group with a dietary and a physical activity component (only this group was included in the analyses); an intervention duration of at least 1 month; a measured mean weight (or BMI) reduction of at least 2% at the end of the intervention; an unsupervised follow-up after the intervention of at least 1 year; at least 20 participants randomised per intervention group; published after 1 January 1990 in English; and having the possibility to calculate the percentage weight maintenance. Exclusion criteria were: studies that included only participants with diabetes, impaired glucose tolerance or another serious disease; weight loss medication; or surgery.

Outcome measure

The primary outcome measure of this study was the percentage of weight loss immediately after the intervention that remained after an unsupervised follow-up. This percentage maintenance was calculated for every intervention group as follows:

$$\text{Percentage maintenance} = \frac{\text{Weight loss from baseline to the end of the unsupervised follow-up}}{\text{Weight loss during the intervention}} * 100$$

The percentage maintenance was corrected for differences in the duration of the unsupervised follow-up period. With the assumption that the percentage maintenance declined linearly during the unsupervised follow-up, the percentage maintenance after 1-year unsupervised follow-up was calculated. In formula, the percentage maintenance after 1 year was calculated as follows: 100% – ((100-% maintenance)/ years of unsupervised follow-up). This adjusted percentage maintenance was used to calculate weight loss after 1 year unsupervised follow-up.

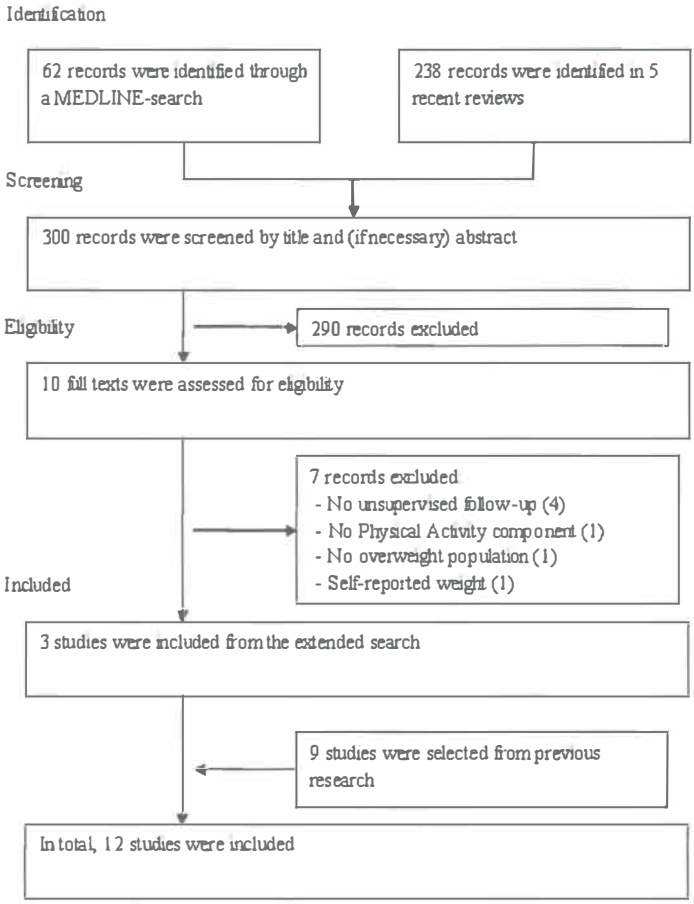


Figure 1 Flow chart of the present search

Because data reported in articles can reflect all participants in an intervention group, participants who completed the intervention and/or participants who completed the unsupervised follow-up, three methods were developed to manage the different data and to calculate weight losses (and thereby the percentage maintenance). For every intervention group one of the following methods (depending on the available data) was used to calculate the percentage maintenance:

Method 1:
Weight losses during the intervention and from baseline to the end of the unsupervised follow-up were calculated for the completers of the follow-up.

Method 2:
Weight losses during the intervention and from baseline to the end of the unsupervised follow-up were calculated for the completers of the intervention. Therefore, weight at the follow-up was calculated for the completers of the intervention using an intention-to-treat analysis under the conservative assumption that participants who dropped out during the unsupervised follow-up regained all their weight.

Method 3:
Weight losses during the intervention and from baseline to the end of the unsupervised follow-up were calculated for all participants who started the intervention. Weight at the end of the intervention was calculated under the assumption that drop outs during the intervention lost the same amount of weight as completers of the intervention (the assumption that drop outs during the intervention lost no weight was not used, because this underestimates weight loss during an intervention resulting in an overestimation of the maintenance percentage). Weight at the follow-up was calculated with an intention-to-treat analysis as described in method 2.

As the intention-to-treat analyses in methods 2 and 3 probably result in a (slightly) underestimated percentage weight maintenance, the first calculation method was the preferred method of choice; otherwise calculation method 2 was used and if data for this method was also unavailable calculation method 3 was used. Authors were contacted by email to provide the best possible data if calculation method 1 was not possible. Author response (with useful information) to email contact about information or data of the study was 67%.
In addition to the analyses between intervention groups, we also investigated weight maintenance within the intervention groups with more than 75 participants at baseline (n=4). Within these interventions groups, the percentage maintenance after 1 year of unsupervised follow-up was calculated for participants with 0-5%, 5-10% and more than 10% weight loss during the intervention. To obtain the necessary data for this analysis, the authors of the four intervention groups were contacted (100% response).

Statistical analyses

The relationship between weight loss during the intervention and the percentage maintenance was investigated by a one-sided Pearson correlation. Differences in the percentage maintenance between categories of <5%, 5-10% and >10% weight loss during the intervention were tested using ANOVA. In these analyses the results were weighted by the square root of the study size (as an approximation of the inverse of the variance of the weight change, which was not always reported). A *P*-value below 0.05 was considered statistically significant. SPSS version 17.0 was used to perform the statistical analyses.

RESULTS

Twenty-two intervention groups of 12 studies met our inclusion criteria and were selected for this review [21-42]. Nine studies were selected from the search previously described in an article [5] and three studies were selected form the extended search (see Figure 1). Four studies from the previously described search were not included in the previous article (because of the use of meal replacements [27, 28, 41, 42] or the lack of results at 1 year after the start of the intervention [31, 32, 40]), but are selected in the present study.

Despite the fact that all interventions contain a dietary and a physical activity component, the content of the interventions differed between the studies (see appendix 1). In general, interventions contained an energy restricted diet and participants received (behavioural) group sessions. The physical activity component existed mostly of an exercise goal or supervised exercise. The characteristics of the selected intervention groups are shown in appendix 1. The mean duration of these interventions was 0.8 years (range 0.2-1.5) and the unsupervised follow-up had a mean duration of 1.1 years (range 1.0-2.0). The most distant measurement of weight was 3.3 years after the start of an intervention.

Of the 22 intervention groups the mean (SD) number of participants was 45 (27), the mean drop out during the interventions was 18% (11) and the mean drop out during the unsupervised follow-up period was 13% (11). The mean baseline weight of these intervention groups was 95 kg (6) and on average 9.5% (4.1) of baseline weight was lost during the interventions. The percentage of the weight loss during an intervention that was maintained after 1 year of unsupervised follow-up ranged from 25% to 88%. On average the percentage maintenance was 54% (18).

Figure 2 shows a scatter plot of the weight loss during an intervention and the percentage maintenance. Weight loss during the intervention and the percentage maintenance were not significantly correlated (r= -0.26, *P*=0.13). In

Table 1 percentage maintenance is shown for intervention groups with 5-10% and intervention groups with >10% weight loss during the intervention. Only one intervention group (88% maintenance) had less than 5% weight loss and therefore this category is not shown. Intervention groups with 5-10% weight loss during the intervention (n=13) maintained on average 55% and intervention groups with more than 10% weight loss during an intervention (n=8) maintained on average 49% (p=0.39). The weight loss after 1 year of unsupervised follow-up differed significantly between these categories, 3.7% and 7.0% respectively (*P*<0.01)

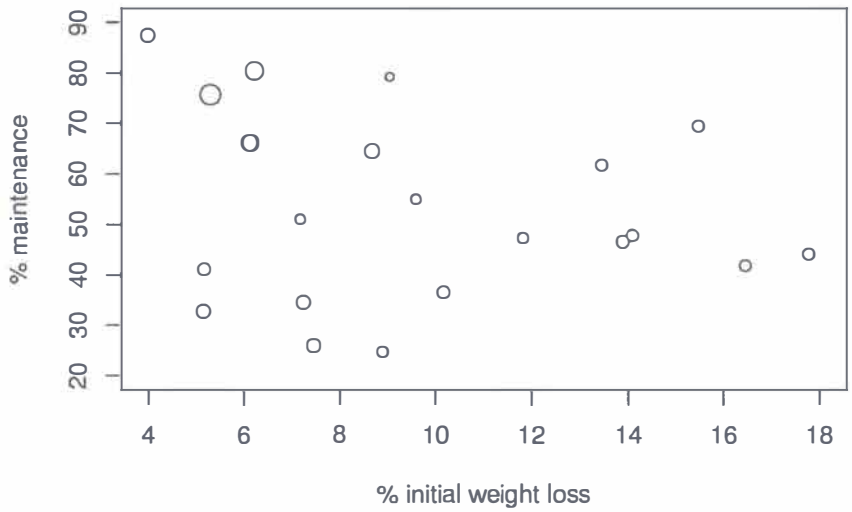


Figure 2 Scatter plot of the percentage maintenance and weight loss during the intervention

Table 1 Percentage maintenance and percentage weight loss after unsupervised follow-up for interventions with 5-10% and >10% weight loss during the intervention

	5-10% weight loss during intervention (n=13)	>10% weight loss during intervention (n=8)
Weight loss during intervention, mean (SD), %	6.8 (1.5)	14.1 (2.5)
Range weight loss during intervention, %	5.1-9.6	10.2-17.8
Maintenance, mean (SD), %	55 (20)	49 (11)
Range maintenance, %	25-80	37-69
Weight loss after 1 year unsupervised follow-up, mean (SD), %	3.7 (1.5)	7.0 (2.1)

In Table 2 weight maintenance is shown within the four intervention groups. In one intervention group participants with a relatively low weight loss maintained more weight loss (they even continued losing weight during the unsupervised follow-up) than participants with a relatively high weight loss during the intervention. Conversely, in the other three intervention groups participants with more than 10% weight loss during the intervention had a comparable or higher percentage maintenance than participants with a lower initial weight loss.

Table 2 Percentage maintenance, within four intervention groups, stratified by weight loss during the intervention.

	0-5% weight loss during intervention	5-10% weight loss during intervention	>10% weight loss during intervention
Burke et al. [21-23]	74% (N=19)	78% (N=20)	84% (N=14)
Cussler et al. [25,26]	63% (N=21)	67% (N=21)	99% (N=12)
Riebe et al. [35-37]	140% (N=13)	55% (N=23)	63% (N=9)
Riebe et al. [35-37]	59% (N=20)	75% (N=15)	71% (N=12)

DISCUSSION

This is the first systematic review investigating the association between weight loss achieved during an intervention and the percentage of this weight loss that was maintained after an unsupervised follow-up period. The results show that the correlation between weight loss during the intervention and the percentage maintenance was not significant. The percentage maintenance between intervention groups with 5-10% and >10% weight loss during the intervention showed also no significant difference, but a greater net weight loss was observed for interventions with >10% weight loss. Additional analyses within intervention groups, stratified by the amount of weight loss, confirm the findings on the percentage maintenance for three out of four intervention groups.

The results also show that an intervention group on average lost 9.5% of their baseline weight during the intervention and that 1 year after the intervention on average 54% of this weight loss was maintained. This percentage maintenance is similar to previous reviews [2, 15], which showed 50% maintenance at 1 year after the end of the intervention and 44% maintenance at 2-year follow-up, respectively.

Moreover, our results show that there was considerable variation in the percentage weight maintenance between the intervention groups (see Figure 2). A variety of factors can influence weight maintenance [43], and the content of the interventions may explain a large part of the variation in percentage maintenance. Therefore, 'best practices' with a focus on prevention of weight regain have to be developed. On this topic no conclusions could be drawn from our study, because of the small number of intervention groups and the poor description of the intervention content in different articles. Wing and Hill [44] identified three behaviours of patients who successfully maintained their weight loss: a low-fat high-carbohydrate diet, regular self-monitoring of weight and engagement in high levels of physical activity (2500-3000 kcal/week or about 1h/day). Elfhag and Rössner [43] identified a number of predictors of long-term weight management (e.g. regular meal rhythm including breakfast, high self-efficacy, social support and self-monitoring of behaviour), many of which could be promoted during treatment with potential for enhancing weight loss maintenance. Other potential targets include developing a flexible restrained approach to diet and lower emotional eating [45], increasing exercise intrinsic motivation [46] and autonomous self-regulation for exercise and weight control [47, 48], and helping participants distinguish between weight loss and weight maintenance skills and behavioural targets [49]. Examples of factors that may leas to weight regain are a history of weight cycling, poor coping strategies, dichotomous thinking, more passive reactions to problems and an external

motivation to lose weight (e.g. pressure from others) [43]. Identifying intervention-related predictors and mediators of long-term weight maintenance in behavioural intervention studies with adequate control groups remains a research priority.

Our data also show that a greater weight loss during the intervention results in greater net weight loss after the unsupervised follow-up. This result is in accordance with the review of Astrup and Rössner [50], which concluded that higher initial weight loss was positively related with a better outcome at 1-5 years thereafter. However, when discussing outcomes of weight control programmes, it is also important to consider additional outcomes besides weight change as criteria for success. First, participants with low percentage of weight maintenance may continue their trend of greater weight regain, which would ultimately result in a lower weight loss in the longer term. Analyses examining the pattern of weight regain after interventions over longer periods of follow-up are needed to provide sufficient insight into this relationship. Second, participants who have a low percentage maintenance fluctuate in their body weight to a higher extent, compared with a high maintenance group, which may have detrimental consequences to health. In a longitudinal study with a follow-up of 7 years, Vergnaud et al. [51] concluded that weight fluctuations (adjusted for relative weight change) are a risk factor for the metabolic syndrome. Therefore, it may be more beneficial for the participants' health to achieve and maintain a lower weight loss instead of losing more weight and regain a substantial part of it (even when total weight loss is more). This needs to be further investigated. Finally, it is suggested that regaining more weight and weight cycling may potentially negatively impact psychological factors, which may exacerbate further weight regain [52, 53]. Further study is needed into the psychological sequels of weight regain following an intervention and its ultimate impact of future weight-related behaviours via factors such as reduced self-efficacy.

A limitation of (systematic) reviews on weight maintenance is the many different data (e.g. data of participants who started the intervention, data of participants who completed the intervention and/or data of completers of the follow-up) that are presented in weight loss articles. This results in a lack of knowledge as to how weight loss was calculated in the reviews and the likelihood that data of the entire intervention group and of the completers of the follow-up may have been merged to calculate weight loss. Contrary to other reviews, we used three clear methods to manage the different data. This ensures better quality of data for subsequent analyses because the method with the least assumptions was chosen.

Besides the explicit methods, a strength of our review is the fact that we were able to perform analyses between and within intervention groups. A limitation in our study is that we assumed in the data calculation that the percentage maintenance diminishes linearly to correct for the duration of the unsupervised follow-up. Additionally, only the weight losses during intervention and weight regain during unsupervised follow-up were known: data on the maximal weight loss (that may have occurred at a point during an intervention or after an intervention had ended) were not available. Therefore maintenance had to be calculated relative to the weight loss at the end of the intervention. However, after correcting the relationship between weight loss during an intervention and percentage maintenance during an unsupervised follow-up for the differences in the duration of an intervention also no significant relation was found. Moreover, the percentage maintenance is (slightly) underestimated in some cases (calculation methods 2 and 3). However, in most of the cases method 1 was used (see appendix 1) and when analyzing methods 2 and 3 without the intention-to-treat method or method 3 under the assumption that drop outs during the intervention lost no weight (and in this way probably overestimating the percentage maintenance in calculation method 2 and 3) a similar pattern was observed. Finally, the results of this study can only be generalised to a healthy adult overweight population, and results may vary for other populations.

In conclusion, no relation between the percentage weight maintenance after 1 year of unsupervised follow-up and weight loss during an intervention was found. However, a greater weight loss during the intervention did result in greater net weight loss after the unsupervised follow-up. From this perspective, 10% or more weight loss should be encouraged and favoured above a lower weight loss. More research is needed to further elucidate the association between weight loss and maintenance on an individual level, to determine optimal weight loss targets and to establish best practices for an optimal maintenance of weight loss.

REFERENCES

1. Wu T, Gao X, Chen M, van Dam RM. Long-term effectiveness of diet-plus-exercise interventions vs. diet-only interventions for weight loss: a meta-analysis. *Obes Rev*. 2009; 10: 313-23.
2. Curioni CC, Lourenco PM. Long-term weight loss after diet and exercise: a systematic review. *Int J Obes (Lond)*. 2005; 29: 1168-74.
3. Douketis JD, Macie C, Thabane L, Williamson DF. Systematic review of long-term weight loss studies in obese adults: clinical significance and applicability to clinical practice. *Int J Obes (Lond)*. 2005; 29: 1153-67.
4. Franz MJ, VanWormer JJ, Crain AL, Boucher JL, Histon T, Caplan W, Bowman JD, Pronk NP. Weight-loss outcomes: a systematic review and meta-analysis of weight-loss clinical trials with a minimum 1-year follow-up. *J Am Diet Assoc*. 2007; 107: 1755-67.
5. Bogers RP, Barte JCM, Schipper CMA, Vijgen SMC, de Hollander EL, Tariq L, Milder IEJ, Bemelmans WJE. Relationship between costs of lifestyle interventions and weight loss in overweight adults. *Obes Rev*. 2010; 11: 51-61.
6. National Heart Lung and Blood Institute in cooperation with The National Institute of Diabetes and Digestive and Kidney Diseases. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The evidence report. 1998.
7. Colorado Clinical Guidelines Collaborative (2007). Adult Obesity Guideline. http://www.coloradoguidelines.org/guidelines/obesity.asp.
8. Anderson JW, Konz EC. Obesity and disease management: effects of weight loss on comorbid conditions. *Obes Res*. 2001; 9 Suppl 4: 326S-34S.
9. Vidal J. Updated review on the benefits of weight loss. *Int J Obes Relat Metab Disord*. 2002; 26 Suppl 4: S25-8.
10. Goldstein DJ. Beneficial health effects of modest weight loss. *Int J Obes Relat Metab Disord*. 1992; 16: 397-415.
11. Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, Keinanen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *N Engl J Med*. 2001; 344: 1343-50.
12. Weiss EC, Galuska DA, Kettel Khan L, Gillespie C, Serdula MK. Weight regain in U.S. adults who experienced substantial weight loss, 1999-2002. *Am J Prev Med*. 2007; 33: 34-40.
13. Catenacci VA, Wyatt HR. The role of physical activity in producing and maintaining weight loss. *Nat Clin Pract Endocrinol Metab*. 2007; 3: 518-29.
14. Fogelholm M, Kukkonen-Harjula K. Does physical activity prevent weight gain--a systematic review. *Obes Rev*. 2000; 1: 95-111.
15. Anderson JW, Konz EC, Frederich RC, Wood CL. Long-term weight-loss maintenance: a meta-analysis of US studies. *Am J Clin Nutr*. 2001; 74: 579-84.
16. Dansinger ML, Tatsioni A, Wong JB, Chung M, Balk EM. Meta-analysis: the effect of dietary counseling for weight loss. *Ann Intern Med*. 2007; 147: 41-50.
17. Egger G. Helping patients lose weight--what works? *Aust Fam Physician*. 2008; 37: 20-3.

18. Ohkawara K, Tanaka S, Miyachi M, Ishikawa-Takata K, Tabata I. A dose-response relation between aerobic exercise and visceral fat reduction: systematic review of clinical trials. *Int J Obes (Lond)*. 2007; 31: 1786-97.
19. Paul-Ebhohimhen V, Avenell A. Systematic review of the use of financial incentives in treatments for obesity and overweight. *Obes Rev*. 2008; 9: 355-67.
20. Richardson CR, Newton TL, Abraham JJ, Sen A, Jimbo M, Swartz AM. A meta-analysis of pedometer-based walking interventions and weight loss. *Ann Fam Med*. 2008; 6: 69-77.
21. Burke V, Beilin LJ, Cutt HE, Mansour J, Williams A, Mori TA. A lifestyle program for treated hypertensives improved health-related behaviors and cardiovascular risk factors, a randomized controlled trial. *J Clin Epidemiol*. 2007; 60: 133-41.
22. Burke V, Beilin LJ, Cutt HE, Mansour J, Wilson A, Mori TA. Effects of a lifestyle programme on ambulatory blood pressure and drug dosage in treated hypertensive patients: a randomized controlled trial. *J Hypertens*. 2005; 23: 1241-9.
23. Burke V, Mansour J, Beilin LJ, Mori TA. Long-term follow-up of participants in a health promotion program for treated hypertensives (ADAPT). *Nutr Metab Cardiovasc Dis*. 2008; 18: 198-206.
24. Carels RA, Darby L, Cacciapaglia HM, Douglass OM, Harper J, Kaplar ME, Konrad K, Rydin S, Tonkin K. Applying a stepped-care approach to the treatment of obesity. *J Psychosom Res*. 2005; 59: 375-83.
25. Cussler EC, Teixeira PJ, Going SB, Houtkooper LB, Metcalfe LL, Blew RM, Ricketts JR, Lohman J, Stanford VA, Lohman TG. Maintenance of weight loss in overweight middle-aged women through the Internet. *Obesity (Silver Spring)*. 2008; 16: 1052-60.
26. Teixeira PJ, Going SB, Houtkooper LB, Cussler EC, Martin CJ, Metcalfe LL, Finkenthal NR, Blew RM, Sardinha LB, Lohman TG. Weight loss readiness in middle-aged women: psychosocial predictors of success for behavioral weight reduction. *J Behav Med*. 2002; 25: 499-523.
27. Fogelholm M, Kukkonen-Harjula K, Nenonen A, Pasanen M. Effects of walking training on weight maintenance after a very-low-energy diet in premenopausal obese women: a randomized controlled trial. *Arch Intern Med*. 2000; 160: 2177-84.
28. Fogelholm M, Kukkonen-Harjula K, Oja P. Eating control and physical activity as determinants of short-term weight maintenance after a very-low-calorie diet among obese women. *Int J Obes Relat Metab Disord*. 1999; 23: 203-10.
29. Jeffery RW, Wing RR. Long-term effects of interventions for weight loss using food provision and monetary incentives. *J Consult Clin Psychol*. 1995; 63: 793-6.
30. Jeffery RW, Wing RR, Thorson C, Burton LR, Raether C, Harvey J, Mullen M. Strengthening behavioral interventions for weight loss: a randomized trial of food provision and monetary incentives. *J Consult Clin Psychol*. 1993; 61: 1038-45.
31. Kukkonen-Harjula KT, Borg PT, Nenonen AM, Fogelholm MG. Effects of a weight maintenance program with or without exercise on the metabolic syndrome: a randomized trial in obese men. *Prev Med*. 2005; 41: 784-90.
32. Borg P, Kukkonen-Harjula K, Fogelholm M, Pasanen M. Effects of walking or resistance training on weight loss maintenance in obese, middle-aged men: a randomized trial. *Int J Obes Relat Metab Disord*. 2002; 26: 676-83.

33. Ramirez EM, Rosen JC. A comparison of weight control and weight control plus body image therapy for obese men and women. *J Consult Clin Psychol*. 2001; 69: 440-6.
34. Rapoport L, Clark M, Wardle J. Evaluation of a modified cognitive-behavioural programme for weight management. *Int J Obes Relat Metab Disord*. 2000; 24: 1726-37.
35. Riebe D, Blissmer B, Greene G, Caldwell M, Ruggiero L, Stillwell KM, Nigg CR. Long-term maintenance of exercise and healthy eating behaviors in overweight adults. *Prev Med*. 2005; 40: 769-78.
36. Riebe D, Greene GW, Ruggiero L, Stillwell KM, Blissmer B, Nigg CR, Caldwell M. Evaluation of a healthy-lifestyle approach to weight management. *Prev Med*. 2003; 36: 45-54.
37. Blissmer B, Riebe D, Dye G, Ruggiero L, Greene G, Caldwell M. Health-related quality of life following a clinical weight loss intervention among overweight and obese adults: intervention and 24 month follow-up effects. *Health Qual Life Outcomes*. 2006; 4: 43.
38. Foreyt JP, Goodrick GK, Reeves RS, Raynaud AS, Darnell L, Brown AH, Gotto AM. Response of Free-Living Adults to Behavioral Treatment of Obesity: Attrition and Compliance to Exercise. *Behavior Therapy*. 1993; 24: 659-69.
39. Skender ML, Goodrick GK, Del Junco DJ, Reeves RS, Darnell L, Gotto AM, Foreyt JP. Comparison of 2-year weight loss trends in behavioral treatments of obesity: diet, exercise, and combination interventions. *J Am Diet Assoc*. 1996; 96: 342-6.
40. Stahre L, Tarnell B, Hakanson CE, Hallstrom T. A randomized controlled trial of two weight-reducing short-term group treatment programs for obesity with an 18-month follow-up. *Int J Behav Med*. 2007; 14: 48-55.
41. Wadden TA, Vogt RA, Andersen RE, Bartlett SJ, Foster GD, Kuehnel RH, Wilk J, Weinstock R, Buckenmeyer P, Berkowitz RI, Steen SN. Exercise in the treatment of obesity: effects of four interventions on body composition, resting energy expenditure, appetite, and mood. *J Consult Clin Psychol*. 1997; 65: 269-77.
42. Wadden TA, Vogt RA, Foster GD, Anderson DA. Exercise and the maintenance of weight loss: 1-year follow-up of a controlled clinical trial. *J Consult Clin Psychol*. 1998; 66: 429-33.
43. Elfhag K, Rossner S. Who succeeds in maintaining weight loss? A conceptual review of factors associated with weight loss maintenance and weight regain. *Obes Rev*. 2005; 6: 67-85.
44. Wing RR, Hill JO. Successful weight loss maintenance. *Annu Rev Nutr*. 2001; 21: 323-41.
45. Teixeira PJ, Silva MN, Coutinho SR, Palmeira AL, Mata J, Vieira PN, Carraca EV, Santos TC, Sardinha LB. Mediators of Weight Loss and Weight Loss Maintenance in Middle-aged Women. *Obesity (Silver Spring)*. 2009; [Epub ahead of print].
46. Teixeira PJ, Going SB, Houtkooper LB, Cussler EC, Metcalfe LL, Blew RM, Sardinha LB, Lohman TG. Exercise motivation, eating, and body image variables as predictors of weight control. *Med Sci Sports Exerc*. 2006; 38: 179-88.
47. Mata J, Silva M, Vieira P, Coutinho S, Andrade A, Teixeira P. Healthy spill-over: Increased exercise motivation improves eating self-regulation during behavioral obesity treatment in women. *Health Psychology*. 2009; (in press).

48. Williams GC, Grow VM, Freedman ZR, Ryan RM, Deci EL. Motivational predictors of weight loss and weight-loss maintenance. *J Pers Soc Psychol*. 1996; 70: 115-26.
49. Cooper Z, Fairburn CG. A new cognitive behavioural approach to the treatment of obesity. *Behav Res Ther*. 2001; 39: 499-511.
50. Astrup A, Rossner S. Lessons from obesity management programmes: greater initial weight loss improves long-term maintenance. *Obes Rev*. 2000; 1: 17-9.
51. Vergnaud AC, Bertrais S, Oppert JM, Maillard-Teyssier L, Galan P, Hercberg S, Czernichow S. Weight fluctuations and risk for metabolic syndrome in an adult cohort. *Int J Obes (Lond)*. 2008; 32: 315-21.
52. Foster GD, Sarwer DB, Wadden TA. Psychological effects of weight cycling in obese persons: a review and research agenda. *Obes Res*. 1997; 5: 474-88.
53. Petroni ML, Villanova N, Avagnina S, Fusco MA, Fatati G, Compare A, Marchesini G. Psychological distress in morbid obesity in relation to weight history. *Obes Surg*. 2007; 17: 391-9

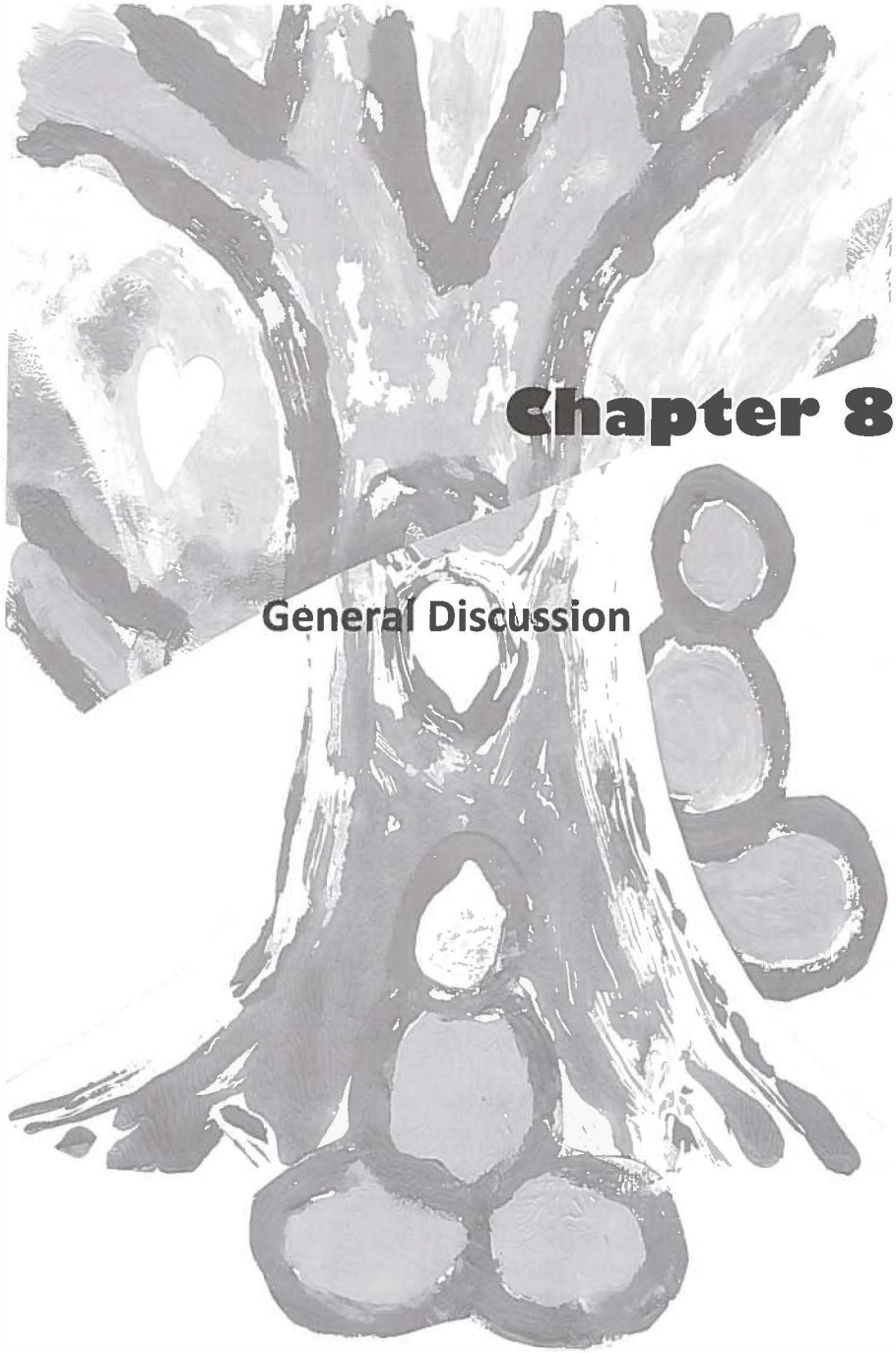
Appendix 1

Author	Group number	Intervention	Duration intervention (y)	Duration unsupervised follow-up (y)	Number participants	Baseline weight (kg)	Method	Percentage weight loss during intervention	Percentage maintenance
Burke et al. [21-23]	1	Participants had group sessions and (if needed) individual sessions. The nutrition component was based on the DASH diet, participants were also encouraged to at least 30 minutes of physical activity on most days.	1.3	2.0	123	87.5	1	5.3	76
Carels et al. [24]	1	Group sessions according to the LEARN programme were given to the participants.	0.5	1.0	23	96.8	1	7.2	51
Carels et al. [24]	2	Participants had 20 group sessions according to the LEARN programme, additional weekly individual meetings about problem solving for participants who did not reach weight loss goals.	0.5	1.0	21	105.0	1	9.6	55
Cussler et al. [25, 26]	1	Group sessions about physical activity, healthy eating, social support and mind/body were given. Participants were encouraged to small changes in eating and physical activity pattern leading to a moderate energy deficit.	0.3	1.0	81	82.0	1	6.2	80
Fogelholm et al. [27, 28]	1	Participants started with a (very) low energy diet. They were instructed to walk 4.2 MJ/week and they followed a low-fat diet. They also attended small group meetings with a supervised walk.	1.0	2.0 [1]	26	91.5	1	15.5	69
Fogelholm et al. [27, 28]	2	Participants started with a (very) low energy diet. They were instructed to walk 8.4 MJ/week and they followed a low-fat diet. They also attended small group meetings with a supervised walk.	1.0	2.0 [1]	27	92.2	1	14.1	48
Jeffery et al. [29, 30]	1	The intervention consisted of behavioural group meetings, a caloric goal of 1000 or 1500 kcal/week and an exercise goal up to 1000 kcal/week.	1.5	1.0	40	89.9	1	5.1	41
Jeffery et al. [29, 30]	2	The intervention consisted of behavioural group meetings, a caloric goal of 1000 or 1500	1.5	1.0	40	87.2	1	7.2	35

		kcal/week, an exercise goal up to 1000 kcal/week and food provision							
Jeffery et al. [29,30]	3	The intervention consisted of behavioural group meetings, a caloric goal of 1000 or 1500 kcal/week, an exercise goal up to 1000 kcal/week and financial incentives dependent on the amount of weight loss.	1.5	1.0	41	91.8	1	5.1	33
Jeffery et al. [29,30]	4	The intervention consisted of behavioural group meetings, a caloric goal of 1000 or 1500 kcal/week, an exercise goal up to 1000 kcal/week, food provision and financial incentives dependent on the amount of weight loss.	1.5	1.0	41	91.8	1	7.5	26
Kukkonen-Harjula et al. [31,32]	1	Participants started with a very low energy diet (preceded and followed by a low energy diet). Thereafter participants received supervised and unsupervised resistance exercise and a low fat diet. Participants also attended small group meetings.	0.7	1.9 [1]	30	104.5	1	13.5	62
Kukkonen-Harjula et al. [31,32]	2	Participants started with a very low energy diet (preceded and followed by a low energy diet). Thereafter participants had supervised and unsupervised walks and a low fat diet. Participants also attended small group meetings.	0.7	1.9 [1]	30	106.0	1	11.8	47
Ramirez et al. [33]	1	Group sessions according to the LEARN programme were given to the participants.	0.3	1.0	40	91.0	1	10.2	37
Ramirez et al. [33]	2	Participants received group sessions for weight control and sessions for cognitive behavioural body image therapy.	0.3	1.0	48	101.1	1	8.7	64
Rapoport et al. [34]	1	Participants received group meetings consisting of cognitive and behavioural methods, education in healthy eating and increasing physical activity. A weight-reducing diet of 1200 kcal/day was provided.	0.2	1.0	38	95.3	2	4.0	88

[1] Weight data of the measurements after 1 year unsupervised follow-up were used to calculate the percentage maintenance.

Author	Group number	Intervention	Duration intervention (y)	Duration unsupervised follow-up (y)	Number participants	Baseline weight (kg)	Method	Percentage weight loss during intervention	Percentage maintenance
Riebe et al. [35 37]	1	Group sessions with behavioural and dietary instructions and supervised exercise were given to the participants. Furthermore they were instructed to exercise outside the program and to eat healthy. In the last part of the study they only received reports on anthropometric, biochemical and dietary variables and some computer generated individualized reports.	0.5	1.5	95	93.3	1	6.1	66
Riebe et al. [35 37]	2	Group sessions with behavioural and dietary instructions and supervised exercise were given to the participants. Furthermore they were instructed to exercise outside the program and to eat healthy. In the last part of the study they only received reports on anthropometric, biochemical and dietary variables.	0.5	1.5	95	89.6	1	6.1	66
Skender et al. [38, 39]	1	Participants had group sessions following the principles of the LEARN programme. Participants were taught the 'help your heart eating plan' and instructed to brisk walk on a vigorous intensity.	1.0	1.0	42	100.1	1	8.9	25
Stahre et al. [40]	1	Participants were provided with group sessions which included elements from cognitive psychotherapy and psycho-education. The nutrition programme consisted of a diet of 1200-1300 kcal/day	0.2	1.5	27	95.1	1	9.0	79
Wadden et al. [41, 42]	1	Participants had behavioural group sessions and supervised aerobic classes. A diet of 900 – 1500 kcal/day was prescribed.	0.9	1.0	31	98.7	3	13.9	47
Wadden et al. [41, 42]	2	Participants had behavioural group sessions and supervised strength training. A diet of 900 – 1500 kcal/day was prescribed.	0.9	1.0	31	96.8	3	17.8	44
Wadden et al. [41, 42]	3	Participants had behavioural group sessions and supervised aerobic classes and strength training. A diet of 900 – 1500 kcal/day was prescribed.	0.9	1.0	29	92.4	3	16.5	42



Chapter 8

General Discussion

GENERAL DISCUSSION

The main objective of this thesis was to investigate the effects of lifestyle counselling by NP compared to usual care from the GP (GP-UC) on body weight and other related parameters in the Groningen Overweight And Lifestyle (GOAL) - study. The associated consequences of obesity on health, health care costs and the negative impact on psychosocial and economic issues make it necessary to counteract the worldwide epidemic. Lifestyle interventions are needed to lose weight but weight regain after initial success is common. Lifestyle counselling aimed at preventing weight gain in stead of (substantial) weight loss may be a better way to achieve long term weight maintenance.

Summary of main findings

After screening and selection 457 participants started with the GOAL intervention (NP group, n: 225; GP-UC group, n: 232). After 1 year 77% of the 201 participants in the NP group and 65% of the 215 participants in the GP-UC group achieved weight maintenance ($P<0.05$) (*Chapter 2*). After 3 years about 60% of the participants in both groups achieved weight maintenance (NP group, n:171; GP-UC group, n:186) (*Chapter 4*). In the NP group, participants who never did an attempt to lose weight during the last five years more often achieved weight maintenance than participants with at least one attempt (12 months: respectively 89% vs. 73%; $P=0.022$, 36 months: 77% vs. 53%; $P=0.003$) (*Chapter 5*).

In men, mean weight losses were in the NP group and GP-UC group respectively -2.3% and -0.1% after 1 year, and -1.4% and -0.2% after 3 years (*P* between groups respectively $P<0.05$, $P=0.149$). In women, in both groups mean weight losses were about -1.6% and -0.9% after respectively 1 and 3 years (*Chapter 2 and 4*). In the NP group, strongest independent predictors of weight change were the amount of weight change between screening and baseline, baseline BMI (higher weight loss in obese persons; after 36 months: -2.4% (CI: -3.9 to -0.8) and dieting history (less weight loss in case of more than 3 recent dieting attempts before baseline; after 36 months: +1.0% (CI: -1.6 to 3.5)) (*Chapter 5*).

After 1 year the NP group spent 33 min/wk more on walking compared to -5 min/wk for the GP-UC group. In both groups nutrient intake changed in positive direction and participants complied more often to dietary guidelines (*Chapter 3*). An intervention effect only after 3 years was found for fasting glucose (NP: -0.02 mmol/L (SD: 0.49), GP-UC: 0.10 mmol/L (SD: 0.53); $P=0.02$). Especially among obese persons the prevalence of impaired fasting glucose differed considerably after 3 years (7% vs. 22%) ($P=0.14$). After 1 and 3 years no

significant differences were found between the NP and GP-UC group for changes in serum lipids and blood pressure (*Chapter 2 and 4*).
The overall satisfaction of the participants was high and the NP was considered to be an expert and motivating in learning and keeping up a healthy lifestyle (*Chapter 6*). The results from the meta-analysis in which 22 lifestyle interventions were included, showed that 54% of the weight loss was maintained after one year of unsupervised follow-up (*Chapter 7)*. In this meta-analyses no clear relation was found between weight loss during a lifestyle intervention and the percentage of weight loss that was maintained after one year of unsupervised follow-up.

Explanation of the results
Despite that the majority of the participants in both groups of the GOAL study achieved weight maintenance after 3 years, the absence of a significant difference between NP and GP-UC group on weight maintenance and weight change is somewhat disappointing. Explanations for the lack of a long term difference between the two study groups need to be mentioned. At first, selecting the participants by inviting them for a screenings visit results in a motivated study group. In line with the ethical committee demands all patients were fully informed about the study purpose and hence they knew beforehand that body weight was assessed as well as adherence to lifestyle advices. This in itself may, through some kind of Hawthorne effect, lead to modified behaviour so that all patients were more adherent than they might have been under other circumstances and this may have diluted any differences between the groups. Second, the attention on health (and body weight) during the measurements in combination with abundant countrywide campaigns for a healthy lifestyle held during the course of the study may besides the visits to the GP also have been responsible for lifestyle changes in the control group. Third, the NP is a relative new position in primary health care. For the GOAL study the NP followed a special training program for counselling but were relatively inexperienced in lifestyle counselling especially computerized counselling according to the GOAL protocol. Due to practical reasons the software program could not be pre-tested. In the NP group 225 participants were spread over eleven NP which implies that per NP relatively fewer participants were treated. The effects of lifestyle counselling according to the GOAL study might be improved when the NP becomes more skilled in lifestyle counselling. These results were also confirmed from our process evaluation within NP 3 months after the start of the invention. NP pointed out that the first times using the computerized program was difficult but after a couple of first visits they get familiar with the program [1]. And fourth, the GPs showed that they were also capable to achieve

weight maintenance for half of their study group. Although the GPs were aware that the patients were participants of a lifestyle study and therefore might be more motivated to pay attention on body weight compared to regular patients. This indicates that the GP can pay a role in preventing (further) weight gain by pointing out the risks of overweight and obesity in visits about obesity related comorbidities like hypertension and dyslipidemia.

Although a long term intervention effect on body weight and weight maintenance was absent we did find that changes in fasting glucose differed in favour of the NP group. Especially among obese persons the prevalence of impaired fasting glucose differed considerably after 3 years (7% vs. 22%), but – due to lack of power in this subgroup analysis– this result was not significant when adjusted for baseline values (P=0.14). This is important in the prevention of diabetes mellitus type 2 which is a prevalent comorbidity in obese persons. The increase in walking in the NP group after the first year of the intervention might be prolonged. Also in other studies was found that even without changes in diet and body weight, physical activity can reduce the incidence of type 2 diabetes [2].

An important predictor of weight maintenance and weight change in the NP group was the number of previous dieting attempts, whereby less attempts were favourable. Biological factors related to weight cycling might play a role but although negative effects of weight cycling have been reported [3-5] no clear results have been reported on the relation between repeated weight losses and mortality and the underlying mechanisms [6-8]. An explanation for the limited success in persons who did more attempts to lose weight is the added knowledge, possibly the NP cannot give new insights on dieting then experienced dieters knew beforehand. Results of the process evaluation of the participants showed that only half of the females, who are more often experienced dieters than males, agreed that the advice on healthy eating added knowledge to their existing knowledge compared to 71% of the males (p=0.02) (*Chapter 6*). The overall satisfaction grade of the intervention will be lower in experienced dieters because the process evaluation showed also that the overall satisfaction of the participants was related to (perceived) success.

It is important to note that participants with a large number of recent attempts to lose weight might be better off not to start to prevent them from another disappointment in weight maintenance. Perhaps this subgroup might be better able to maintain their weight by group sessions or by counselling with more attention on psychological aspects. Also for the NP it will be more motivated to counsel patients with a reasonable prospect for success in obesity treatment in combination with the complementary health care costs.

Weight maintenance versus unlimited weight loss

The percentage maintenance of weight loss in the NP group after 36 months was 55%, this is comparable with the results from our review in *Chapter 7*. Although the mean follow up time in the GOAL study (1.1 year (range 1.0 – 2.0)) differed from the review, in the GOAL study we had supervised in stead of unsupervised follow up and we did not primarily aimed at losing weight. Within the group of successful participants after one year (n=136) the percentage maintenance of weight loss was 65% (1 year: -3.7%; 3 years: -2.4%). For participants who never did an attempt to lose weight five years prior to the study (n=71) the percentage maintenance of weight loss was 68% (1 year: -2.6%; 3 years: -1.8%) in contrast with 26% maintenance of weight loss for participants who did at least one attempt to lose weight (n=87) (1 year: -1.8%; 3 years: -0.5%). The results from Table 2 in combination with our review showed that more than 5% weight loss does not lead through a higher regain of weight compared to a lower percentage weight loss. In fact, successful weight losers achieved a higher percentage maintenance of weight loss in combination with a higher net weight loss after 3 years.

Table 2 Changes[a] in main outcome variables at 1 and 3 years follow-up within the NP group, stratified for four categories of weight change after 1 year

	Successful weight losers (≤ -5%) (n=37)	Weight losers (-4.9% to -0.9%) (n=68)	Stabilisers (-1% to 1%) (n=31)	Weight gainers (> 1%) (n=35)
Body weight, mean (SD), % change after 1 year	-8.8 (3.1)	-2.7 (1.1)	0.1 (0.5)	3.6 (2.1)
Body weight, mean (SD), % change after 3 years	-5.7 (5.3)	-1.5 (4.6)	-0.6 (3.6)	3.7 (5.2)
Maintenance of weight loss	65%	56%	-600%	103%

[a]Changes are calculated as the value at 1 or 3-years follow-up minus the value at baseline

On the basis of above mentioned results, our goal on weight maintenance to prevent participants from further weight gain in stead of losing weight are with respect of effects on health not recommendable above losing weight. Notwithstanding that for persons with previous attempts to lose weight other

advises or another treatment will be better to prevent them from disappointing results.

Strengths and limitations

The strengths of the GOAL study are the randomised controlled design, the prolonged follow-up and the large study population with an equal division in gender. The use of an intervention which is not time-intensive and expensive and quite feasible in a primary care setting and that the software program can easily be used at other locations are also benefits of our study. It's worthwhile to achieve lifestyle changes in this middle-aged, relatively low cardiovascular risk population with a moderate mean BMI to prevent weight gain and thereby prevent future accelerated increase of cardiovascular risk factors.

Limitations are baseline differences between the NP en the GP group and randomization at patient level in stead of at practice level. The visits to the NP after the first year were with a low frequency and may not be sufficient to sustained weight loss. Overall, achieving weight maintenance was in both groups not influenced by the mean number of visits. The intervention was not completely conducted according the study protocol with respect to the number of phone calls. The majority of the participants filled in that they did not have contact with their NP by phone (63%) in contrast with the 5 planned sessions. However, a few NPs indicated to the investigators that they substituted telephone contacts for face-to-face contacts, because they preferred face-to-face contact due to practical issues of the telephone calls (e.g. not (easily) being able to contact the participants and a higher adherence to face-to-face visits). This may lead to incorrect conclusions about the effectiveness of the intervention. However, these alterations in the program were only conducted by a few NPs and therefore the protocol was followed in a large extent. This is in accordance with the number of visits from calculated out of the registration system from the general practice locations (*Chapter 4*). Another limitation is the percentage of drop out after 3 years. After 1 the drop out was low (9%) but rose to 22 % after 3 years. Although this amount relatively low in accordance to other lifestyle intervention more attention should be paid on the prevention of early withdrawal. The results on changes in food intake and physical activity were only known after 1 year. It is essential to investigate these results also after 3 years to determine if the difference in fasting glucose between the NP and the GP-UC group was a consequence of the (sustained) increase in time spent on walking in the NP group which was found after 1 year. Also without losing weight, the increased time spent on walking is very important in the prevention of diabetes mellitus type 2.

Implications for future research

Although the effects of lifestyle counselling by NP compared to GP usual care were not impressive we also cannot conclude that lifestyle counselling by NP is not useful especially because after 3 years an intervention effect was achieved on fasting glucose. In comparison to the Dutch population where an average increase in BMI of 0.05 kg/m^2 per year (between 1981 and 2004) was described by Gast *et al* [9] we found a decrease of -0.4 kg/m^2 in the NP and -0.2 kg/m^2 in the GP-UC group. Also according to the guidelines on cardiovascular risk management lifestyle counselling is recommended in patients with hypertension and dyslipidemia[10]. The prevalences of hypertension and dyslipidemia are high and these diseases were mainly treated by the GP which means that lifestyle counselling is indicated for a large part of the population in primary care. The NP can specialize in lifestyle counselling and the GP can spend more time on other patients' needs.

It's important to investigate the effects on the longer term like 5 or 6 years after the start of the intervention because little information is available on such a time span. It's interesting to examine if the achieved weight maintenance will sustain also without contact sessions and if the NP group achieved better results than the GP-UC group. The latter may be occurring because the NP paid attention on preventing relapse to former lifestyle patterns during the visits.

Besides the above mentioned topic for further research it is interesting to perform a cost effectiveness of the achieved weight maintenance. The NP spends more time on the participants but overall is cheaper than the GP and the NP might be less prone for drug treatment than the GP. It's worthwhile to have more insight in the cost effectiveness of the GOAL study before further implementation.

Implications for primary health care

The Dutch College for Health Insurance (CVZ) reported in 2009 that a combined lifestyle intervention (GLI[1]), existing of advice and counselling on diet, physical activity and behavioural changes are necessary for the prevention of overweight and obesity and that this combination is more effective than the independent strategies [11]. Subsequently in 2010 the cost and effectiveness calculations (in Dutch : "budgetimpactanalyse") showed that after 10 years of GLI a positive balance of about 50 million Euros will be reached within health care. When also taking social perspective into account the incomes in 10 years is estimated to be 192 million Euros [12]. Although assumptions had to be made for this calculation the advice is given to embed the GLI in the regular part of

[1] In Dutch known as "gecombineerde leefstijlinterventie" which is abbreviated in this thesis as GLI

the health insurance (in Dutch: "basisverzekering") without a limitation of a single consultation. In the standard of care obesity (in Dutch: "zorgstandaard obesitas") which will be authorized in November 2010 other definitions of the high risk population were made resulting in a smaller part of the population to be considered for GLI. The standard of care obesity is set by the partnership obesity (In Dutch: Partnerschap Overgewicht Nederland; PON) which was founded in 2008 as an initiative of the department of health care. The partnership is founded for collaboration of a larger number of health professionals, partners involved in the daily care for persons with overweight and obesity.

It's not investigated what the minimal required competency for health care professional per component of the GLI is. This is planned for 2011 and will result in a functional description per component and not for specific positions in health care. This means that several health care professionals e.g. nurse practitioners, physiotherapists, dieticians, general practitioners can provide guidance to those with a high weight related health risk for one but also for all components of the GLI. Further research is necessary for the most effective way of lifestyle counselling with respect to counselling by more professionals at the same time versus one professional. The GOAL study showed that one professional can achieve weight maintenance, just a small part of the participants was referred to a dietician (NP group: 18%; GP-UC group: 13%) and this did not influenced the results (*Chapter 4*). The GP can play an important role as a central health care professional for a good alignment between the other professionals whether the treatment is (partly) outside the general practice. Besides this our study showed that primary care, with a relative cheap and feasible intervention, is an ideal setting to initiate and encourage lifestyle changes so GLI can be conducted in primary care.

In November 2010 the NHG (The Dutch College of General Practitioners) published a Practice Guideline Obesity for Adults and Children [13] (in this thesis no attention will be paid on the separate parts in this guideline for children) in which it is stated that the GP can delegate the mentioned activities to a NP or practice assistant (the GP remains responsible for quality). Less evidence from high quality Dutch trials was available for the development of this guideline but now the results from the GOAL study can be used for further refinement. The results from the GOAL study show that (as described before) more attention should be paid on the number of previous attempt to lose weight of the patients.

Different from the GOAL study, in the new guideline lifestyle counselling is only recommended for persons with a considerable increased cardiovascular risk. In the GOAL study participants with a BMI between 25 and 29.9 kg/m^2, a normal

waist circumference and e.g. a serum cholesterol level of 5.7 mmol/L without further co-morbidity were eligible but will not indicated for lifestyle counselling according to the new NHG guideline on obesity. This means that when using the GOAL intervention in a population with a higher cardiovascular risk greater health efforts can be achieved.

The contact sessions at the GP are every 3 months in the first 2 years of the treatment, and are independent of contact sessions with other health care providers who are also involved in the treatment. If the GP is the only lifestyle coach, the number of contact sessions in the beginning of the treatment might be not according to the patients' needs. The first period is important to make a good start with lifestyle changes, and the need for information and coaching will be higher than in the latter (maintenance) phase of the treatment.

The number of contact sessions in the GOAL study (mean number of visits after 3 years, NP: 18; GP: 4) did not lead through weight loss (this was not aimed), even not in the NP group whereby software guided lifestyle counselling was provided by a trained NP (although changes in fasting glucose differed in favour of the NP group). The advices on diet and physical activity in the GOAL study and the guideline are comparable but in the new GP guidelines the positive effects of cognitive-behaviour therapy should be mentioned (also in the guideline of the Dutch Institute for Healthcare Improvement this is mentioned as a part of the lifestyle intervention [14]). According to a review of Shaw this will increase weight loss compared to an intervention on diet and exercise, particular in the long-term [15]. Although the GOAL intervention is based on the principles of cognitive-behaviour therapy, referring to a specially trained psychologist might be a good supplement to the current lifestyle advices because the lifestyle intervention in the GOAL study was not sufficient for weight loss.

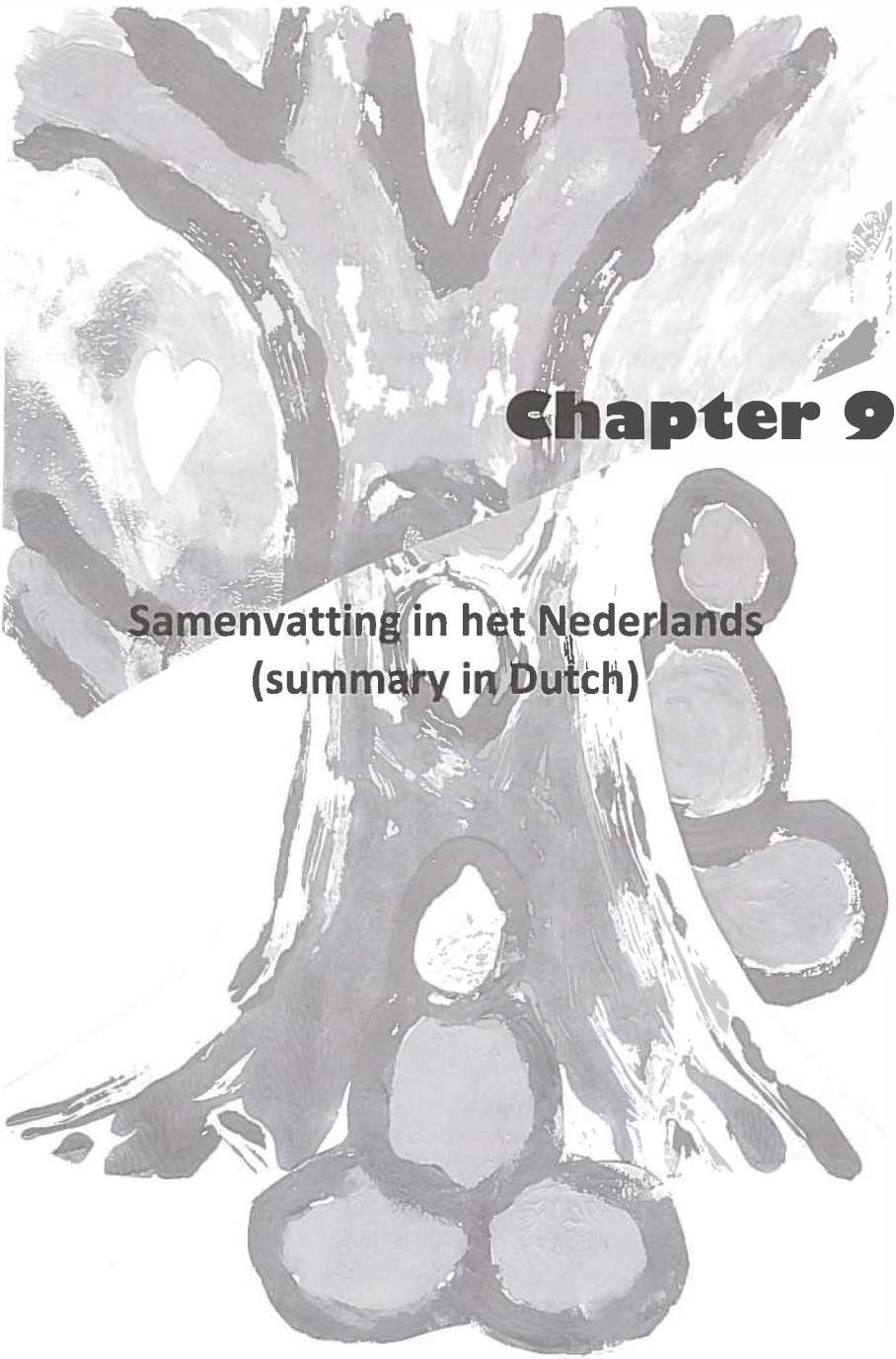
In real practice setting more attention should be paid on overweight and obesity as part of the treatment of hypertension and dyslipidemia and other weight related diseases like diabetes mellitus type 2 and arthritis. Caused by study circumstances as described before our participants were all motivated to some extent also in the standard of care obesity is it described that screening on weight related health risk can be routinely or opportunistic. This means that persons were dependent on the interest and preferences of the health care professional whether attention is paid on their body weight. Body weight and height to calculate BMI should be measured and the weight related health risk should be determined regularly. A part of the participants (especially men) did not consider them self as overweight or obese despite a BMI > 25 kg/m^2. Therefore they might not be aware of the consequences on health of their body weight so that an active approach is necessary to prevent persons from

further weight gain. More attention should be paid on prevention; in guidelines lifestyle counselling is only recommended for persons with an increased risk.
After 5 years the Covenant Obesity did not achieve in decreasing the prevalence of overweight and obesity in the Netherlands although in adults the prevalences did not increase (the number of children with overweight is possibly still rising). Further, many successful interventions have started, the number of partners who signed the covenant is doubled and importantly the obesity epidemic has been stressed as key topic. In 2010 a new covenant (In Dutch: Convenant Gezond Gewicht) was signed which will run till 2015. For this time span a local integral approach is chosen with more attention to unity between interventions in different settings like school, labour and leisure time [16].

General Conclusion
Prevention of (further) weight gain in the long term in primary care setting by NP and GP can be achieved for more than half of the participants with a relative cheap and feasible intervention which can be easily implemented. For sustained weight loss more intensive or other treatment is necessary as it is for participants with a history of dieting.

REFERENCES

1. Blokstra A. *Procesevaluatie GOAL-project*. Bilthoven: RIVM; 2006.
2. Laaksonen DE, Lindstrom J, Lakka TA, et al. Physical activity in the prevention of type 2 diabetes: the Finnish diabetes prevention study. *Diabetes*. 2005;54(1):158-165.
3. Hamm P, Shekelle RB, Stamler J. Large fluctuations in body weight during young adulthood and twenty-five-year risk of coronary death in men. *Am J Epidemiol*. 1989;129(2):312-318.
4. Lissner L, Odell PM, D'Agostino RB, et al. Variability of body weight and health outcomes in the Framingham population. *N Engl J Med*. 1991;324(26):1839-1844.
5. Olson MB, Kelsey SF, Bittner V, et al. Weight cycling and high-density lipoprotein cholesterol in women: evidence of an adverse effect : A report from the NHLBI-sponsored WISE study. *Journal of the American College of Cardiology*. 2000;36(5):1565-1571.
6. Brownell KD, Rodin J. Medical, metabolic, and psychological effects of weight cycling. *Arch Intern Med*. 1994;154(12):1325-1330.
7. Field AE, Malspeis S, Willett WC. Weight cycling and mortality among middle-aged or older women. *Arch Intern Med*. 2009;169(9):881-886.
8. Jeffery RW. Does weight cycling present a health risk? *Am J Clin Nutr*. 1996;63(3 Suppl):452S-455S.
9. Gast GCM, Frenken FJM, van Leest LATM, Wendel-Vos GCW, Bemelmans WJE. Intra-national variation in trends in overweight and leisure time physical activities in The Netherlands since 1980: stratification according to sex, age and urbanisation degree. *Int J Obes*. 2006;31(3):515-520.
10. Dutch College of General Practitioners. *NHG-Standaard cardiovasculair risicomanangement [Guideline Cardiovascular Risk Management]*. Houten: Dutch College of General Practitioners; 2006.
11. Van der Meer FH, Ligtenberg G, Staal PC, et al. *Preventie bij overgewicht en obesitas: de gecombineerde leefstijlinterventie*. Diemen: Dutch College for Health Insurance (CVZ); 2009.
12. Van der Meer FH, Couwenbergh BTLE, Enzing JJ, Ligtenberg G, Staal PC. *De gecombineerde leefstijlinterventie: kosten, opbrengsten en de praktijk*. Diemen: Dutch College for Health Insurance (CVZ); 2010.
13. Van Binsbergen JJ, Langens FNM, Dapper ALM, et al. NHG-Standaard Obesitas. *Huisarts en Wetenschap*. 2010;53(11):609-625.
14. Dutch Institute for Healthcare Improvement (CBO). *Diagnostics and treatment of obesity in adults and children*. Utrecht. 2008.
15. Shaw K, O'Rourke P, Del Mar C, Kenardy J. Psychological interventions for overweight or obesity. *Cochrane Database Syst Rev*. 2005(2):CD003818.
16. Convenant Overgewicht. *Eindverslag Convenant overgewicht 2005 - 2010. "Fit for the Future"*. Den Haag 2010.



Chapter 9

Samenvatting in het Nederlands (summary in Dutch)

SAMENVATTING

Inleiding

Sinds 1980 stijgt het aantal mensen met overgewicht (body mass index (BMI) groter dan 25 kg/m^2) in alle bevolkingsgroepen, ongeacht geslacht, leeftijd en urbanisatiegraad. Overgewicht verhoogt het risico op diabetes mellitus type 2, hart- en vaatziekten, verschillende vormen van kanker en artrose. Ofschoon sommige mensen meer aanleg hebben voor gewichtstoename dan anderen, ligt de basisoorzaak van overgewicht in een onjuiste balans tussen energie-inname (voeding) en energieverbruik (lichamelijke activiteit). Een gunstige verandering van de leefstijl draagt dus bij aangewichtsvermindering en heeft daarnaast – ook los van de effecten op het lichaamsgewicht – een positief effect op de gezondheid. Leefstijlveranderingen zijn nodig om af te vallen maar aankomen na eerst afgevallen te zijn komt regelmatig voor. Leefstijlaanpassingen ter preventie van gewichtstoename in plaats van (substantiele) gewichtsafname zouden een betere manier kunnen zijn om gewichtstabilisatie op de langere termijn te kunnen bereiken. Een goede leefstijladvisering voldoet aan een aantal voorwaarden, zoals continuering van zorg, aandacht voor voeding én lichamelijke activiteit en een zekere intensiteit. Wat de meest (kosten)effectieve manier van leefstijladvisering is, die ook goed toepasbaar is in de praktijk, is echter nog niet helder. In de praktijk blijkt verandering van gedrag lastig en bekende barrières zijn een gebrek aan tijd en kennis bij de huisarts en onvoldoende continuïteit van begeleiding. Deze barrières worden grotendeels omzeild wanneer niet de huisarts maar de praktijkondersteuner de leefstijladvisering uitvoert.

GOAL study

Vanaf 2005 is daarom de GOAL (Groningen Overweight and Lifestyle) study opgezet. Deze studie onderzoekt de lange termijn effecten van leefstijladvisering door de praktijkondersteuner (PO groep = interventiegroep) in vergelijking met de gebruikelijk zorg van de huisarts (HA groep = controlegroep). De deelnemers krijgen een lichamelijk onderzoek, bloedonderzoek en vullen vragenlijsten in voorafgaand aan de studie (= beginmeting), na 1 jaar (= eerstejaarsmeting) en na 3 jaar (=derdejaarsmeting). Het onderzoek is uitgevoerd in huisartspraktijken op 11 verschillende locaties in Groningen, Friesland en Drenthe bij mensen met overgewicht en obesitas (BMI tussen 25 en 40 kg/m^2) en daarnaast hypertensie en/of hyper-/dyslipidemie. De praktijkondersteuner gebruikt een geprotocolleerde leefstijlmodule (software), die uitgaat van verschillende fasen van gedragsverandering en het opstellen van individuele leefstijldoelen voor de patiënt. In opeenvolgende consulten wordt op een gestructureerde manier aandacht geschonken aan

kennisoverdracht en bewustwording van leefstijl. Een individueel behandelplan wordt opgesteld en vervolgens worden de ervaringen geëvalueerd en leefstijldoelen worden –indien nodig– bijgesteld. In de PO groep waren in het eerste jaar 4 consulten en 1 telefonische consult gepland, in jaar 2 en 3 zijn per jaar 1 consult en 2 telefonische consulten gepland. De deelnemers uit de HA groep kregen in ieder geval 2 consulten (1 na de beginmeting en 1 na de eerstejaarsmeting) bij de huisarts en ontvingen daarnaast de gebruikelijke zorg.

Doelen

Het belangrijkste doel van dit promotie-onderzoek is het onderzoeken van het effect van leefstijladvisering door een praktijkondersteuner in vergelijking met de gebruikelijke zorg van de huisarts op het lichaamsgewicht, de middelomtrek, de bloeddruk, cholesterolgehalte en het nuchterglucose gehalte van het bloed, lichamelijke activiteit en voedsel inname. Daarnaast proberen we factoren te indentificeren die voorspellers zijn van succesvolle gewichtstabilisatie op de lange termijn. Om mogelijkheden voor verdere implementatie van de leefstijlmodule te onderzoeken en te achterhalen wat de ervaringen van de deelnemers in de interventiegroep waren, hebben we een procesevaluatie uitgevoerd in deze groep. Om de bevindingen van de GOAL study in een breder perspectief te kunnen plaatsen, is ook een meta-analyse gedaan. Hierbij hebben we systematisch onderzocht wat de relatie is tussen het gewichtsverlies tijdens een leefstijlinterventie en het behoud van dit gewichtsverlies na een follow up periode zonder begeleiding.

Definities gewichtsstabilisatie en behoud van gewichtsverlies

In dit proefschrift is gewichtsstabilisatie, als primaire doel van de GOAL study, gedefinieerd als: minder dan 1% gewichtstoename tussen de beginmeting en de derdejaarsmeting. Deelnemers die dit doel bereiken worden beschouwd als succesvolle deelnemers.

Het percentage behoud van gewichtsverlies binnen de GOAL study is gedefineerd als gewichtsverlies vanaf de beginmeting tot de derdejaarsmeting gedeeld door het gewichtsverlies vanaf de beginmeting tot de eerstejaarsmeting en vervolgens vermenigvuldigd met 100.

Het percentage behoud van gewichtsverlies is in de meta-analyse gedefinieerd als: gewichtsverlies vanaf de beginmeting tot het einde van de follow op periode zonder begeleiding gedeeld door het gewichtsverlies gedurende de interventie en vervolgens vermenigvuldigd met 100.

Belangrijkste resultaten

Na screening en selectie zijn 457 deelnemers in de eerste helft van 2006 gestart met de GOAL study (PO groep, n: 225; HA groep, n: 232). Na 1 jaar is 77% van de 201 deelnemers in de PO groep en 65% van de 215 deelnemers in de HA groep op gewicht gebleven ($P<0.05$) (*Hoofstuk 2*). Na 3 jaar blijkt dat in beide groepen ongeveer 60% van de deelnemers gewichtsstabilisatie heeft bereikt (PO groep, n:171; HA groep, n:186) (*Hoofstuk 4*) . In de PO groep bereikten de deelnemers die de afgelopen 5 jaar geen afvalpoging hebben gedaan vaker gewichtsstabilisatie dan deelnemers met tenminste één afvalpoging (1 jaar: respectievelijk 89% versus 73%; $P=0.022$, 3 jaar: respectievelijk 77% versus 53%; $P=0.003$) (*Hoofstuk 5*).

Bij de mannen waren de gemiddelde gewichtsafnames in de PO groep en de HA groep respectievelijk -2.3% en -0.1% na 1 jaar; -1.4% en -0.2% na 3 jaar (*P* waarde tussen de twee groepen, $P<0.05$, $P=0.15$). Bij de vrouwen was de gemiddelde gewichtsafname in de twee studiegroepen ongeveer gelijk (na 1 jaar -1.6% en na 3 jaar -0.9%) (*Hoofstuk 2 en 4*). De gewichtsverandering in de PO groep werd vooral voorspeld door de hoeveelheid gewichtsverandering tussen de screening en de beginmeting, het gewicht bij aanvang van de studie (grotere gewichtsafname voor deelnemers met een BMI tussen 30 en 40 kg/m^2, na 3 jaar, -2.4% (95% BHI: -3.9 tot -0.8)), en lijnhistorie (minder gewichtsafname bij meer dan 3 recente lijnpogingen voorafgaand aan de studie, na 3 jaar, +1.0% (95% BHI: -1.6 tot 3.5) (*Hoofdstuk 5*).

Na 1 jaar zijn de deelnemers uit de PO groep ruim een half uur per week meer gaan wanden terwijl de deelnemers uit de HA groep hier gemiddeld 5 minuten per week minder aan hebben gespendeerd ($P=0.05$). In vergelijking met de beginmeting, voldoen zowel de deelnemers in de PO groep als in de HA groep na 1 jaar vaker aan de voedingsnormen en veranderde de voedingsinname in positieve richting (*Hoofdstuk 3*). Voor nuchter glucose werd naar 3 jaar een interventie effect gevonden (PO: -0.02 mmol/l (SD: 0.49), HA: 0.10 mmol/l (SD: 0.53); $P=0.02$). Vooral in obese deelnemers daalde de prevalentie van gestoorde glucose tolerantie (nuchter glucose > 6,0 mmol/l) aanzienlijk na 3 jaar (22% versus 7%) ($P=0.14$). Na 1 en 3 jaar werden geen significante verschillen gevonden tussen de PO en de HA groep wat betreft veranderingen in lipiden en de bloeddruk (*Hoofdstuk 2 en 4*).

Uit de procesevaluatie kwam naar voren dat de deelnemers over het algemeen tevreden waren. Daarnaast werden de praktijkondersteuners beschouwd als experts en motiveerden ze de deelnemers in het aanleren en vasthouden van

een gezonde leefstijl (*Hoofdstuk 6*). Uit de meta-analyse, bestaande uit 22 leefstijl interventies, blijkt dat 54% van het gewichtsverlies is behouden na 1 jaar follow up zonder begeleiding. Verder is er uit deze meta-analyse geen duidelijke relatie gevonden tussen de hoeveelheid gewichtsverlies gedurende de leefstijlinterventie en het percentage gewichtsverlies dat behouden is gebleven na 1 jaar follow up zonder begeleiding (*Hoofdstuk 7*).

Verklaring van de resultaten

Ondanks dat de meerderheid van de deelnemers in beide groepen gewichtstabilisatie heeft bereikt, is de afwezigheid van een significant verschil in gewichtsverandering en percentage gewichtsstabilisatie tussen de PO en de HA groep wat teleurstellend. Dit kan als volgt verklaart worden; er is sprake van gemotiveerde deelnemers doordat ze actief zijn benaderd via een uitnoding voor een screeningsbezoek en daarnaast (volgens de richtlijnen van de medisch etische toetsingscommissie) ook volledig zijn geïnformeerd over de doelstellingen van de studie. Hierdoor zouden de deelnemers zich anders zijn gaan gedragen dan in de normale omstandigheid. Ten tweede is er in de media ook veel aandacht geweest voor een gezonde leefstijl wat in de HA groep in combinatie met de consulten bij de huisarts ook tot gedragsveranderingen hebben geleid. Ten derde is de praktijkondersteuner een relatief nieuwe functie en vereist het werken met een computergestuurde leefstijlmodule enige oefening. Dit bleek ook uit de procesevaluatie waarin de praktijkondersteuners aangaven dat de eerste paar keer dat de module gebruikt werd dit als moeilijk werd maar dat ze daarna gewend raakten aan deze andere manier van werken. En ten slotte laten de huisartsen ook zien dat ze in staat zijn om gewichtsstabilisatie te bereiken voor de helft van de deelnemers uit hun groep. Dit laat zien dat de huisarts een rol kan spelen in het voorkomen van verdere gewichtsstijging door hun patienten bewust te maken van het risico van overgewicht en obesitas tijdens een consult over aan obesitas gerelateerde comorbiditeiten zoals hypertensie en dislipidemie.

Algemene conclusie

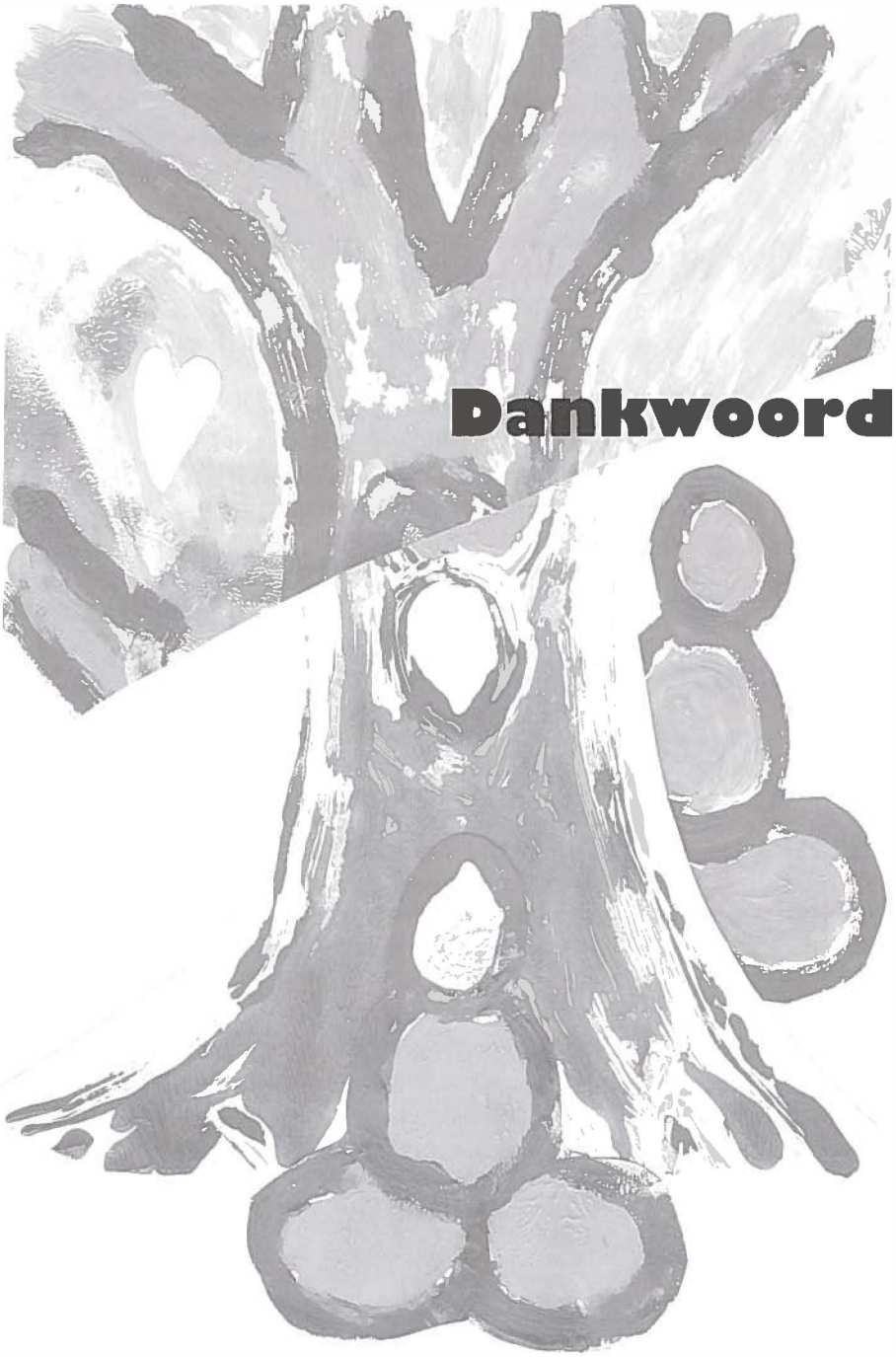
Gewichtsstabilisatie in de eerste lijn, door zowel de praktijkondersteuner als de huisarts, is mogelijk met behulp van een relatief goedkope, goed uitvoerbare en makkelijk te implementeren interventie. Een intensievere of ander soort behandeling is nodig voor mensen die al vaker afvalpogingen hebben gedaan en om gewichtsverlies te bereiken.

Huisartsen

Lijst van deelnemende huisartsen

DEELNEMENDE HUISARTSEN

Huisartsenpraktijk Lewenborg, te Groningen
Huisartsenpraktijk Drenthe en Veenstra, te Groningen
Huisartsenpraktijk de Vecht, te Groningen
Huisartsenpraktijk Het Bolwerk, te Franeker
Huisartsenpraktijk De Wilgen, te Veenwouden
Huisartsenpraktijk De Compaenen, te Heerenveen
Huisartsenpraktijk Arentsen & Groeneveld, te Lemmer
Huisartsenpraktijk Echtenerbrug, te Echtenerbrug
Huisartsenpraktijk Statenlaan, te Roden
Huisartsenpraktijk Groen en Witteveen, te Roden
Huisartsenpraktijk Mantingh, te Roden
Huisartsenpraktijk Brink 3, te Roden



Dankwoord

DANKWOORD

Op de laatste pagina´s van dit proefschrift ligt eigenlijk de basis van de hele GOAL study. Als eerste zou ik daarom alle deelnemers ontzettend willen bedanken voor hun (vrijwillige) participatie. Zonder jullie zou het niet mogelijk zijn geweest! En zonder deelnemende huisartsen en praktijkondersteuners was het ook niet gelukt; fijn dat jullie hebben meegewerkt! Zeker van de praktijkondersteuners werd het nodige gevraagd; er vond bijscholing plaats en een nieuw softwareprogramma (met kinderziektes en installatieproblemen) moesten jullie onder de knie krijgen. Dit is prima gelukt en jullie kritisch meedenken heb ik echt gewaardeerd. Vervolgens verdienen de huisartspraktijken een groot compliment voor het faciliteren van de GOAL study. Er kon in de praktijken altijd een plekje gevonden worden zodat de onderzoeksmedewerkers (studenten) de metingen bij de deelnemers konden verrichten. Dank voor jullie behulpzaamheid en zeer gastvrije ontvangst!

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